EPIDEMIOLOGY RESEARCH NEEDS RELATED TO THE RADIOIFREQUENCY ENERGY FROM WIRELESS PHONES

COOPERATIVE RESEARCH AND DEVELOPMENT AGREEMENT
(CRADA)

Between
FOOD AND DRUG ADMINISTRATION'S
CENTER FOR DEVICES AND RADIOLOGICAL HEALTH
(CDRH)

and

CELLULAR TELECOMMUNICATIONS INDUSTRY ASSOCIATION (CTIA)

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DR. OWEN: Good morning all. Thank you for coming back. I think we had an excellent day of input yesterday and also got a lot of important questions that we'll need to follow up -- that Abiy and I will need to follow-up in the time after this meeting, you know, with other investigators, people that were here earlier, and then checking back in with you all.

We talked about yesterday trying to revisit the -- I mentioned yesterday that today we'd try and re-visit some of what we talked about yesterday. And also, Leeka made the excellent suggestion that we could get into some specifics we maybe hadn't discussed in terms of ideas of kinds of methodological studies to address particular issues, so getting down to a little more detailed pieces.

So, of course, the thing to do here is to look for the gaps and to identify things to address them.

As I put up there on the board, it seemed like the clear message from our discussion yesterday was that we needed to learn a lot about exposure assessment.

You know, there were comments yesterday to the effect that all the work that's done before is of little or no utility because of problems with exposure assessment and other shortcomings, and that any future

work really would be in need -- would need to be based on

advances in the exposure assessment knowledge.

Now, I've tried to draw up a list of things based on yesterday's discussion that would need to be captured in a collection of studies maybe on exposure assessment, or parts of studies pertaining to exposure assessment. This would involve use of technology like the software-modified phones or even the more sophisticated dos phones that take other measurements.

Some of the parameters that -- I'll just read through some of the parameters I've got down. Modulation scheme, phone model, transmission mode, position, which is a function of several things: the tissue being exposed, distance, the angle at which the phone is held. Power level of transmission in any of these modes, both peak and conventional averages. Of course, the duration and its different manifestations.

Then beyond that, other dosimeter information, perhaps. It wasn't -- I have a question mark here in my notes, because it wasn't clear to me whether this pertained to phone handsets or had more to do with

other RF exposures.

Of course, information -- a wealth of information collected through the use of questionnaires, both of the primary subject, as well as perhaps proxies. Again, this wasn't clear to me how that might need to be

worked in; maybe not at all except for when you get to doing case control study or maybe -- maybe people thought that it could be useful to study that from a methodological perspective, before you came to depend on it.

Billing records. And, of course, back to the questionnaire, you need all kinds of -- a whole lot of things that have been fairly well established in the development of other questionnaires about, you know, the type of usage, the environment, other RF exposures, other comparative effect modifiers, along with some things that we don't really have to get into I think that level of detail on.

So we -- it looks like we need that kind of information for a variety of user categories, you know, different ages, including pediatric users, different activities, you know, both occupational and otherwise.

And that all this exposure assessment, due to the handsets, would need to be evaluated in the context of or, you know, in addition to evaluation of exposures from base stations or other RF exposures, again both from occupational and public perspectives.

And in the end, you want to have a handle on, you know, what tissue is getting the highest dose

rates, what those dose rates are, and I think what you

really would like to know out of doing all of this is, what the relative impact of these various parameters is on the -- those sort of bottom line questions of what tissue is being exposed to how much.

Because that's a lot of information to collect, and clearly you could not collect all of that information for an entire cohort, for instance. We had some discussion of sampling or sub-cohort analysis or rotation, you know, different approaches. But, nonetheless, you know, you're not able to collect all that information all the time for all of the cohort.

So if you can reduce the -- if you can find out the relevant impact of the various parameters, then, presumably, you can collect the important ones for more people. You know, if you can narrow down the amount of -- the piece of information you need to really define your exposure, assess your exposure, in a cohort, for instance, then the fewer things you have to find out, the more people you can find it out about.

DR. BOWMAN: If you got a person's

permission to access something that -- data that was available for the general public, say driver's license information or phone billing records, how much beyond, you know, Social Security number and address and phone number and age, gender, would -- beyond the basic demographics

and locator information can you get about a person that would be, you know, useful for exposure assessment?

DR. OWEN: You mean without a questionnaire?

DR. BOWMAN: Right. I mean, sort of the bottom line of the cohort study is that to get the full power from the cohort, you have to be able to have the same data on everybody.

We're pretty much down on studies that just rely on billing records as your basic information. And that would seem to be about as detailed of information that you could possibly get from records that would be relevant to exposure.

DR. KHEIFETS: But it's probably not that. I mean, it's probably --

DR. BOWMAN: Well, it's certainly something.

DR. KHEIFETS: It's something. It's a description. And, I mean, I think you would have -- I don't think we really know. I mean, I think we'd have to do a lot of methodologic work to really find out how well those billing records really reflect the exposures --

DR. BOWMAN: Um-hmm.

DR. KHEIFETS: -- and what are the right,

even, you know, kind of questions to ask in the future to

try to adjust for -- you know, I mean, there are some obvious things that, you know, were you the only one using the phone and for what --

DR. BOWMAN: Right.

DR. KHEIFETS: -- percentage of the time the phone was used by you, rather than somebody else. But other than that, we really don't really know, do we?

DR. LOTZ: All billing records really give you is time and frequency of calls, right? Duration and frequency.

DR. KHEIFETS: Duration.

DR. BOWMAN: Right.

DR. KHEIFETS: Yeah.

DR. BOWMAN: We'll get --

DR. OWEN: Although, I guess --

DR. BOWMAN: You would get time for each call is what you'd -- well, you do for long distance. But for local, you don't even get that too much.

DR. LOTZ: To the nearest minute, I think, at least our bill gives you the duration of each call, what time of day it was --

DR. KHEIFETS: Incoming too?

DR. LOTZ: Yes.

DR. KHEIFETS: I think mine --

DR. LOTZ: It doesn't tell you the source

of the incoming, but it tells you how long it lasted.

DR. KHEIFETS: It tells you how long it is.

DR. LOTZ: But that's basically cause that adds to your minutes. So that's what's --

DR. KHEIFETS: Um-hmm. Um-hmm.

DR. OWEN: Well, we have to -- I think we would have to consider that the minimum amount of information that would be available --

DR. LOTZ: Yeah.

DR. OWEN: -- from the provider.

DR. LOTZ: Right.

DR. OWEN: Potentially there's more information available. Unless you're talking about getting the billing information from the user, in which case you do really have to depend on what the user's getting.

DR. BOWMAN: Well, what we've been saying --

DR. OWEN: If you're getting it director from the provider is --

DR. BOWMAN: What we've been saying up to now, if you're dealing with a cohort of hundreds of thousands of people, that the only thing that you can do

across that entire cohort would be things that you can get

from records.

DR. OWEN: So you're saying that with a cohort of that size, you could not even do a questionnaire of everybody?

DR. BOWMAN: Well, if you had enough money you could.

DR. OWEN: Yeah.

DR. BOWMAN: But that's -- I mean, I did -- the childhood leukemia study that I had was, you know, hundreds of subjects. And if you're talking about hundreds of thousands of subjects, you're talking budgets in the multi-millions --

DR. OWEN: Um-hmm.

DR. BOWMAN: -- to interview everybody. But we would --

DR. KHEIFETS: But when you were talking about hundreds of subjects, you were talking about budgets in multi-million.

DR. BOWMAN: Yeah, or several million. We're talking tens of millions of dollars.

DR. KHEIFETS: But there are other issues. There are just not the question of the money. There are

also issue of participation and, you know, how many people you really going to get, and organization. I mean, there are other issues too that are quite difficult. I

mean, maybe not unsurmountable, but certainly very difficult, problematic.

DR. BEARD: I think clearly the information that is best would come from the modified phones. But I gather that they won't be available in sufficient quantity, and even if they were, they'd cost too much to give to the full cohort.

DR. BOWMAN: Yeah. But, I mean, if you --

DR. LOTZ: Yeah.

DR. BOWMAN: -- think of the logistical problems of interviewing hundreds of thousands of people, getting phones in their hands and getting them back, as well as the cost of the phones, is another big budget hit, if you're talking about the entire cohort.

DR. LOTZ: Yeah.

DR. BEARD: This might suggest a good place to do one of the limited studies that Leeka suggested, is to get part of the cohort with those phones in their hands, and compare their usage to their billing records and extrapolate to the rest of the cohort from there.

DR. BOWMAN: Well, I think, if I were to make a priority list of recommendations, number one would be a software-modified phone study in the U.S. And it

wouldn't even have to be necessarily linked to a cohort.

It'd just use the IARC, the Interphone protocol, and do it in the U.S., so that you have something to compare U.S. usage patterns to the countries in Interphone.

DR. KHEIFETS: Yes. So it would be to use -- to get their billing records, to get their interview, and to get the phone, and to compare those three ways of assessing exposure or --

DR. OWEN: Is the billing record in the Interphone?

DR. BOWMAN: Yeah.

DR. OWEN: Okay.

DR. BOWMAN: Yeah. I actually have a draft protocol that you're welcome to copy. Oh, wait a minute. I guess I was going to check and see if --

DR. OWEN: Yeah, you -- I think you were.

DR. LOTZ: Yesterday we weren't welcome to copy it.

DR. OWEN: Yeah, times change.

DR. BOWMAN: I'm sure she'll --

DR. OWEN: I was -- I mean, that's not a --

DR. BOWMAN: -- it's not a problem. But I do want to not make presumptions.

DR. OWEN: Well, it's reasonable to expect

that a protocol for such a study would be similar to, but

maybe not identical to the Interphone ones. So, I mean, we would certainly be informed by that design.

Whether it included the billing records or not, it certainly it sounds like to me, it makes sense that if you did this study, the one that you just suggested, that there's no reason not to try and include the billing records in whatever questionnaire you want to come up with, either an existing one or a new one.

One of the things that wasn't -- I guess you could only get from a questionnaire or with an observational study like the small one that FCC people do was, you know, to -- when people are using it, where are they holding it, standing on the street corner and looking at people through binoculars to see how they're holding the phones, I mean, it's been done.

DR. LOTZ: Well, not only that, but the modified phone can give you that same kind of --

DR. BOWMAN: Um-hmm.

DR. LOTZ: -- information.

DR. BOWMAN: The Motorola one.

DR. OWEN: Yeah, only the Motorola dos phone.

DR. LOTZ: Yeah.

DR. OWEN: And it's -- I don't know

25 offhand how it responds, if it's, you know, in a belt clip

versus --

DR. LOTZ: No, I don't know that either.

DR. OWEN: Things like that.

DR. LOTZ: But I can --

DR. OWEN: Although the mode of operation could tell you some -- I mean, certainly --

DR. LOTZ: I thought that Balzano said that there was an equivalent phone built for Nokia and Ericksen --

DR. BOWMAN: Right.

DR. LOTZ: That each -- that the IARC Study would have --

DR. OWEN: About a hundred phones.

DR. LOTZ: -- some of each.

DR. OWEN: That is what he said. But I think --

DR. BOWMAN: But the ones for the other companies did not have the orientation --

DR. OWEN: I think they're only --

DR. LOTZ: Okay.

DR. OWEN: -- only software-modified. They don't have that like --

DR. LOTZ: Okay.

DR. OWEN: -- capacitive coupling distance detection and all that.

DR. LOTZ: All right.

DR. OWEN: But certainly, if it doesn't have it already, it wouldn't require much to determine whether the thing had a hands-free device plugged into it.

DR. LOTZ: Right.

DR. OWEN: At which point --

DR. LOTZ: Yeah, that --

DR. OWEN: -- nobody would be holding it to their head while they were using a hands-free device.

DR. LOTZ: Right.

DR. OWEN: So that would be a pretty clear indicator. Then the only question would be whether the hand being exposed or the pelvic region, or where -- breast pocket, wherever, which is the kind of thing you'd have to get out of questionnaires, I guess.

DR. BOWMAN: Well, I think if the phone was operating and it wasn't at the head, the capacitive coupling devices should certainly be at abnormal levels.

DR. OWEN: If it was transmitting, yeah, that's true, they would -- they would basically tell you

you're beyond some distance from the head.

DR. LOTZ: Well, actually, I was thinking the other way, that if it's clipped right to the belt, say for example --

DR. OWEN: It depends on which way it's

facing.

DR. LOTZ: -- or in a little holster --

DR. OWEN: Maybe.

DR. LOTZ: -- that it would be pretty high capacitive coupling. You might have better coupling to the torso than you would to the head, depending on how the phone --

DR. BOWMAN: All I was just saying is that I would think that the class of coupling would be different enough for other than at the head that you could tell.

DR. OWEN: You could somehow tell.

DR. LOTZ: Oh, that's a good idea -- good point.

DR. OWEN: Yeah, that's probably true.

DR. LOTZ: That's true.

DR. BOWMAN: So if it's transmitting and it's not at head levels of coupling, then you would assume --

DR. OWEN: Yeah, you're probably right.

DR. BOWMAN: -- that something else is going on, either it's data transmission or headset.

DR. OWEN: Right. So that's just a data analysis issue. It's not a functionality --

DR. LOTZ: In fact, even those two I would

think would be different enough that might be -- might be --

DR. BOWMAN: Could be; I don't know.

DR. LOTZ: I don't know either.

DR. BOWMAN: We'd have to ask Q.

DR. LOTZ: Yeah.

DR. BEARD: You may be able to tell from orientation too, if it's got a little gravity sensor in there, if it's not left or right. You know, usually in a belt it's straight up, so --

DR. OWEN: Yeah. Right, cause you did say it had the --

DR. LOTZ: Yeah.

DR. BOWMAN: My geometry is still struggling with seeing how you could tell from a gravity sensor whether it's left or right.

DR. LOTZ: He referred to it as an accelerometer. But is that the same thing, or something a little different?

DR. OWEN: Well, that would -- it's going to detect movement.

DR. BOWMAN: It just seems to me to be -- relative to the Earth, it doesn't matter; left or right

doesn't matter.

DR. OWEN: Um-hmm. I mean --

DR. LOTZ: Well, it had to do -- the chip was not in the phone symmetrically. So somehow it had to do with whether it was right-side up or upside down, but not -- chip is the wrong term.

DR. OWEN: Because you don't hold the phone --

DR. LOTZ: The sensor.

DR. OWEN: As Brian was saying, you don't hold the phone vertically when you -- or you don't hold it at the same angle with respect to the axis of the Earth, depending on which ear you're on.

DR. LOTZ: Well, if you turn it --

DR. BOWMAN: Yeah.

DR. LOTZ: -- around to the other ear, you're likely to be upside down on the orientation of the phone.

DR. OWEN: Combined with the capacitive readings which tell you which --

DR. BOWMAN: Okay. Now that I can get, I believe.

DR. LOTZ: Anyway --

DR. OWEN: Anyway --

DR. LOTZ: -- presumably it could be done.

DR. OWEN: Yeah.

DR. BOWMAN: Somebody's --

DR. LOTZ: Whether we can figure it out or not.

DR. OWEN: It doesn't matter whether we can design the phone or not --

DR. LOTZ: That's right.

DR. OWEN: -- that's somebody else's task.

DR. BOWMAN: I'm still not the exposure assessment person. So if I can't understand what it's doing, I don't --

DR. OWEN: You're not going to be comfortable with it --

DR. BOWMAN: Right.

DR. OWEN: -- yeah. So when I ran through that list of pieces of data, did anybody -- I guess nobody thought of one that I didn't say, or they would have volunteered it. Modulation scheme, phone model, mode of operation, position, which is distance, side, angle, all

that stuff. Power, peak and average; time duration.

DR. BOWMAN: Now, there is an issue in the dosimetry that, like Brian was saying, especially when you're doing experimental dosimetry, you're limited as to the number of orientations you can good the data on, while over a range of users, a much wider array of orientations are used with the phones.

So Joe Viart from French Telecom was --

had this procedure for computer generating SAR profiles and getting average SARs for the phones in a wide array of orientations and then averaging over that in some way.

DR. OWEN: Actually, the dos phone has that interval, where when it detects the position of the phone, it as part of the development of that, they, on the fly, calculate the SAR --

DR. BOWMAN: Really?

DR. OWEN: -- the peak SAR, or something, based on that. Yeah. If you go --

DR. BOWMAN: Wow.

DR. OWEN: If you go to that web site, it demonstrates that the phone being moved continuously --

DR. BOWMAN: Um-hmm.

DR. OWEN: -- like this. And then in a split screen, it's got basically an SAR plot that's going up and down, depending on the position of --

DR. BOWMAN: Right.

DR. OWEN: -- the phone. So it's an essentially --

DR. BOWMAN: Wow.

DR. OWEN: -- continuous function.

DR. LOTZ: Where's that web site?

DR. OWEN: It's at MIT. It's been there

a

25 couple years. Like I said, we'll have to see if we can

find it and see if it's still there. But, certainly, Motorola would be able to provide us with that --

DR. BEARD: For your exposure assessment, you're not -- how detailed, as far as position, are you worried about? I mean, I don't think there's any way in that exposure phone to say, you know, that right here, you know, behind the ear the exposure went up, versus in front of the ear it went down. I mean, they must be taking some sort of an average.

DR. OWEN: I think they're trying -- I think they're actually basing it on peak. I mean, the idea was, you're attuned into the, you know, compliance question, cause, certainly, yeah, you're not going to be at the same time trying to plat what intra-cranial region is getting the maximum in a study like that.

DR. LOTZ: I don't think there's --

DR. OWEN: I mean that's not -- I don't think that's something you would try and attack in a study like this.

DR. LOTZ: Russ, you know, I agree with the desirability of all those things. But in reality, when you come down to looking at this cohort for health outcomes, if we know, with some confidence, or at

least

24 reasonable estimate of their relative even time of use

--

25 DR. BOWMAN: Right.

DR. LOTZ: -- and maybe stratify that in terms of, you know, phones that have a factor of a lot different SARs, I don't see much point in worrying about whether the SAR of this particular phone is 1.4 versus this one being 1.2, or something like that.

So I guess what I'm saying is, in the end, in terms of what we really would, for the major study in terms of health outcomes of the cohort, I'm not sure we could ever sort of utilize this much information.

DR. OWEN: Well, I guess what I was trying to say earlier was, I thought one of the outcomes of doing this kind of detailed study of a smaller group was, it would tell you what were the most important parameters for

getting, you know, your rougher assessment of exposure on a larger study, because you wouldn't be collecting all these parameters from a whole cohort.

DR. LOTZ: Right.

DR. OWEN: And you also want to know what that exposure is, not only what is the most important parameter affecting it, you want to know what that parameter amounts to in terms of a maximum or a peak or a cumulative, or whatever you --

DR. LOTZ: Yeah. It seems like one of the most difficult things in terms of the duration, the ongoing tracking of the cohort would be to follow their

changes in technology. I mean, I don't mean that they make a drastic change. But they just get a different phone.

DR. BOWMAN: Right. And that's a key --

DR. LOTZ: In this country they go from a dual mode phone to a totally digital phone. Or, you know --

DR. OWEN: Or go from not using a hands-free device to using a hands-free device.

DR. LOTZ: That's right.

DR. BOWMAN: Um-hmm.

DR. LOTZ: And those are -- that's going to require periodic interaction with them of some -- in some way.

DR. BOWMAN: Oh, right. Cause you're not going to get what phone model they're using necessarily off the billing records. Will you?

DR. OWEN: Yeah, I guess I'm --

DR. LOTZ: I don't think so.

DR. BOWMAN: I don't know.

DR. LOTZ: I don't know if -- I don't know if the phone company has that data and doesn't show it. But I don't think it normally --

DR. BOWMAN: If it's now you just take

your card and put it in and that programs the phone to

hook up with your service provider.

DR. LOTZ: Yeah.

DR. BOWMAN: The service provider wouldn't know what phone it's coming from, I wouldn't think.

DR. OWEN: What I was seeing in my mind was a division between a discussion of just exposure assessment studies, sub-studies --

DR. LOTZ: Okay.

DR. OWEN: -- versus the data that you would collect when you were doing a cohort study, a perspective cohort study. Both things are important to discuss. But I was seeing this --

DR. LOTZ: That's fine.

DR. OWEN: Certainly, I would assume you'd be collecting a lot more information on the sub-study than you would be in the long run.

DR. LOTZ: Oh, yeah. Right.

DR. OWEN: And the goal is -- I was thinking that the sub-study would tell you what you were supposed to be collecting in the long run, from --

DR. BOWMAN: Right.

DR. OWEN: -- the larger cohort.

DR. LOTZ: That's fine.

DR. BOWMAN: And certainly with the soft -- the Motorola dosimeter phone, that has so much more

capability, and although it's just being delivered now, that if a study was done in the U.S., not only, you know, would it provide a comparable data that could be compared with the Interphone countries, but it also would -- there is enough variability there and enough different variables there to have a U.S. investigator look into that.

DR. KACZMAREK: A comment on Interphone. The Europeans, for a number of reasons, particularly the Scandinavians, can mount a cohort study more easily than we can in the U.S. Basically it's a smaller population. It's less mobile. Things like cancer registries have complete coverage of the entire country, which we lack in the U.S. I mean, the SEERS system only covers certain states and certain counties; people move out of those areas, they're lost.

So I think that's another good reason for us to be participating.

DR. LOTZ: Right.

DR. KACZMAREK: Because if there is a cohort study, realistically, it may be more easily mounted in Scandinavia than in the U.S. And, again, Johansen already, you know, did one in Denmark.

DR. OWEN: But Interphone is a case control study.

DR. KACZMAREK: No. But as we're talking

about things like we want to do as exposure assessments, right, to determine -- to make the determination merely that --

DR. OWEN: Oh, okay.

DR. KACZMAREK: -- the exposures in the U.S. are comparable to those in Europe.

DR. OWEN: Right.

DR. KACZMAREK: And I think that's relevant because, in reality, a cohort study could be more readily mounted in Scandinavia than the U.S.

And then the question would be, well, are those results from Scandinavia applicable in the U.S.

DR. OWEN: Okay. So a possible place you could end up is that in Europe you've got a cohort study, a case control study, and the exposure assessment component that's in --

DR. KACZMAREK: Right.

DR. OWEN: -- Interphone. And that here you might -- in the U.S. you might only have the exposure assessment from Interphone --

DR. KACZMAREK: And case control studies --

DR. OWEN: -- and that would be your --

DR. KACZMAREK: -- could be mounted

pretty

25 readily in the U.S. as well.

DR. OWEN: Yeah.

DR. KACZMAREK: Again, because there's a limited number of people. We can get informed consent from all the study subjects. There isn't a need for long-term follow-up. So it shouldn't be problematic. Obviously, case control studies, Inskip and Muscat have already done the -- we know that's feasible; they've already been done.

DR. OWEN: Right.

DR. KACZMAREK: So the U.S. should certainly be participating in terms of a case control -- case control studies, as a plural, I would hope.

DR. LOTZ: Right.

DR. BOWMAN: There's one distinction --

DR. KACZMAREK: A cohort study would be more challenging.

DR. BOWMAN: -- in case control studies, is whether they're hospital-based or population-based. And there the Scandinavians use not only their nationwide tumor registries, but also their census allows them to draw controls from the population, as well as draw cases from the entire country.

Now, to what extent they're doing that, I can't tell you off the top of my head. But that makes it

a step closer to a cohort study, because you're drawing

your controls from the entire country.

DR. KHEIFETS: Yeah. I mean, most of the time they do just record studies. They don't do -- I don't think the participation is that great in Sweden either. I think they must doing record-based studies, because they have their occupational information. They have census information that includes occupational information on a regular basis.

DR. BOWMAN: Right.

DR. KHEIFETS: And so most of their studies are just linking the different registries.

DR. BOWMAN: Right.

DR. KHEIFETS: That's a very efficient way, but it's very limited information. It usually doesn't have --

DR. BOWMAN: Right. Well, it --

DR. KHEIFETS: -- the individual information. Although, there are exceptions. Of course, there are other studies too.

DR. BOWMAN: Well, for Interphone, they start with a nationwide registry --

DR. KHEIFETS: And then --

DR. BOWMAN: -- as a sampling frame, the sample controls. Then they have to get participation.

DR. KHEIFETS: Right.

DR. BOWMAN: And, of course, they'll lose some there. But they're starting out with a population-based sample as opposed to a hospital-base approach, which is what Inskip and Muscat did. As well as some of the other countries in the Interphone are also doing hospital-based. And it's different in the different countries.

DR. KHEIFETS: Yeah, um-hmm. How certain or how knowledgeable are we about other RF exposures? Are they totally negligible?

DR. BOWMAN: No. Like Greg was talking the other day, especially, you know, when you're doing a broad sample of people, there's always a chance that you could get a, you know, an RF heater operator or somebody that uses walkee-talkees, or an amateur radio operator. There's always that chance. And that's what --

DR. LOTZ: Yeah. I mean --

DR. KHEIFETS: So is that another point in the gap is --

DR. OWEN: Yeah, I think --

DR. KHEIFETS: -- other RF exposures?

DR. OWEN: Yeah. In fact, that was one of the questions I was getting ready to was, was do we know enough about what investigations are going on right now to know what's missing in terms of doing those other, you

know, basically any non-wireless phone RF exposures?

DR. KHEIFETS: No. But the question here is whether in the wireless studies one has to try to --

DR. OWEN: Oh.

DR. KHEIFETS: -- get information on other RF exposures.

DR. OWEN: Yeah. And that was where -- the reason I mentioned the dosimeter and then also, presumably, parts of the questionnaire --

DR. KHEIFETS: Right.

DR. OWEN: -- where you have to try and get a handle on that. But I thought the dosimeter would -- I mean, would you integrate the dosimeter only when you found somebody in the questionnaire that you thought was going to have other sources of exposure?

DR. KHEIFETS: Well, I think that, you know, it's -- initially, you want just to get some -- just have the dosimeter information in a random sample --

DR. BOWMAN: Right.

DR. KHEIFETS: -- to just to first to see --

DR. BOWMAN: Get a baseline.

DR. KHEIFETS: Just to get, yeah, the baseline. I mean, I don't know what -- I mean, are there any other sources? Microwave ovens? I don't know. I

mean, if people -- if somebody stands really close. I

mean, I know you get a lot of ELF fields if you stand really close to microwaves.

DR. LOTZ: Yeah, you get a lot more ELF than you get RF.

DR. BOWMAN: The EPA used to have --

DR. LOTZ: The qualifier I always put is, you know, unless the door is damaged, which -- which happens. I mean, I've --

DR. KHEIFETS: Um-hmm.

DR. LOTZ: You know, I've had somebody say to me, well, I work in a fast-food place and the, you know, sometimes the door actually falls off, and we just stick it back on, you know, kind of thing. And that's probably spraying a lot of RF around. But for the most part --

DR. OWEN: Based on the WEAC (phonetic) studies, that seems to be pretty rare.

DR. LOTZ: Yeah.

DR. OWEN: They've been doing surveillance of ovens for a number of years. And they basically have been talking about stopping doing the surveillance, cause they're not finding things --

DR. LOTZ: Not finding anything.

DR. OWEN: -- going out of compliance --

DR. LOTZ: Yeah, right.

DR. OWEN: -- for the standard.

DR. LOTZ: Right.

DR. KHEIFETS: What about computers, do you get any RF?

DR. BOWMAN: That's in the ELF range. That's --

DR. KHEIFETS: Oh, you don't get any --

DR. BOWMAN: Another source would be broadcasting antennas in the neighborhood and AM/FM, TV. EPA used to have a van that was traveling around neighborhoods recording RF. What's his name?

DR. LOTZ: Ed Repitroli (phonetic).

DR. BOWMAN: Yeah. He's now working out of Cleveland.

DR. LOTZ: Right.

DR. BOWMAN: He was involved with some of that.

DR. KHEIFETS: I mean, I kept thinking that RF exposures, I mean, it's going to be harder, but maybe it's not going to get harder than ELF, if ELF is everywhere and RF is not. Maybe it's --

DR. LOTZ: The only way that RF is everywhere is through wireless phones.

DR. KHEIFETS: Um-hmm.

DR. LOTZ: Otherwise, RF is relatively

limited to local particular groups of people, workers or people living in apartments opposite a high tower where there's a, you know, a broadcast antenna or something like that. Those are relatively, you know, uncommon.

That's why -- that's part of the reason why, you know, I don't think there's much RF epidemiology out there, is because it hasn't been this -- up till now, it hasn't been this eviquitous kind of --

DR. KHEIFETS: -- exposure, yeah.

DR. LOTZ: -- exposure.

DR. KHEIFETS: Yeah. So that should make it much easier. What about hospitals, do people in the hospitals get any?

DR. BOWMAN: Well, they're now using wireless --

DR. BEARD: There's some telemetry systems.

DR. BOWMAN: -- LAN type situations for monitoring patient care --

DR. LOTZ: Yeah.

DR. BOWMAN: -- at high-tech hospitals.

DR. BEARD: Yeah, wireless medical telemetry. And there's been a lot of problems with what you mentioned yesterday, locating the antennas on the

roofs of hospitals because of the zoning, interfering with

the medical LANs. So that's a separate issue.

DR. KHEIFETS: But that's also related -- I mean, LANs are certainly everywhere. SO there might be --

DR. BOWMAN: Wireless LANs are new.

DR. KHEIFETS: Well, but they will be everywhere. I mean, there's --

DR. BOWMAN: I agree. I agree.

DR. KHEIFETS: So maybe, you know, there --

DR. LOTZ: And that's an unknown, I guess, in my mind at this point, is how much power those are actually transmitting. I've heard different things.

DR. OWEN: Right.

DR. LOTZ: You know, some concern. Others say, no, they're real low power, it doesn't matter.

DR. OWEN: Right. I mean, if you're sitting --

DR. LOTZ: And I just don't know.

DR. OWEN: -- in this room, and you look -- when you walk out in that hallway and you look out the door, you can see a broadcast antenna. You know there's a base station for cell phones somewhere close by. Then if you installed a wireless LAN in here, what of the relative

contributions to your RF exposure of those different

things.

DR. LOTZ: And I --

DR. OWEN: For the wireless LAN, we don't have a good handle on that.

DR. LOTZ: You know, I don't know whether some of the industry people have a better handle on that or not. But I -- but we don't at this point.

DR. BEARD: How sensitive are the RF personal dosimeters that are coming out? Would they be sensitive enough to identify people in --

DR. LOTZ: I don't --

DR. BEARD: -- other exposure groups?

DR. LOTZ: I don't think they'll pick up most of that. But I -- but I don't know the answer. That was a good question, what can they pick up. Because I know --

DR. BOWMAN: Well, I thought it depends on what they're trying to look at. If they're looking at compliance with IGNA (phonetic) --

DR. LOTZ: Yeah.

DR. BOWMAN: -- no.

DR. LOTZ: Right. And that's where I think -- because if you take -- if you take, for example, when we went to measure near a school for a base station, you could not see anything with the standard compliance

surveillance-type equipment. Only when we took a tuned antenna with a spectrum analyzer in there, could we quantify and detect the levels.

And I think you're going to get that with most of the -- you know, even most locations around a very strong broadcast antenna.

DR. BOWMAN: Um-hmm.

DR. LOTZ: Unless you're close or unless it's on a building and you're in another building that's sort of beam level kind of thing --

DR. BOWMAN: To cover the full dynamic range of our environment would seem to me you needed -- you just couldn't digitize your output. Even if you had mobile ranging, you'd have to -- there's an ELF meter with a positron that has logarithmic bins. It only tells you what bin you're in. It doesn't give you much --

DR. LOTZ: Yeah. I was just trying to get at the utility of the possible use of these personal dosimeters.

DR. OWEN: And there was mention yesterday of one that's newly developed by NARDA.

DR. BOWMAN: Right. That's what I'm --

DR. OWEN: Is that one also --

DR. BOWMAN: -- sort of speculating. And

I'm saying, if the NARDA one is aimed at compliance with

the IGNA standard --

DR. OWEN: Then there still would not be --

DR. BOWMAN: -- it would not pick up these lower level or shorter range --

DR. KHEIFETS: So I guess we say, if there are meters available, or one maybe should develop meters, whatever we would want to phrase it, that you catch, you know, to measure load exposures, you know, there should be a survey -- it doesn't have to be a large survey -- just to ascertain what are all the sources.

DR. OWEN: Right. And I guess you can back up one step from that and do the hypothetical that I was just talking about, where you basically, you know, set up a wireless LAN in this room and --

DR. KHEIFETS: Sure.

DR. OWEN: -- without a personal dosimeter, but, you know, with more cumbersome equipment --

DR. KHEIFETS: Sure.

DR. OWEN: -- you could do that kind of environmental survey as opposed to a --

DR. KHEIFETS: Sure.

DR. BOWMAN: Yeah. That's a real valid

way to do it. You don't always have to do personal

exposures. When you're starting out, you're probably better off not, that you do spot area measurements around the environment synchronized to sources. And that gives you, you know, the ranging that you need to even design a personal dosimeter that can cover everything.

And that the stop measurements can be done with the existing equipment.

DR. OWEN: Right. Like you said, you can make it attuned to whatever it is you're trying to pick up --

DR. BOWMAN: Right.

DR. OWEN: -- you know, the channels and whatnot.

DR. BOWMAN: Right.

DR. OWEN: Or you can scan. But --

DR. BOWMAN: Yeah.

DR. OWEN: Yeah.

DR. BOWMAN: And there is already a lot of information about existing technologies, what their magnitudes and frequencies are.

DR. OWEN: Um-hmm.

DR. BOWMAN: There's a real nice survey article on that.

DR. OWEN: Yeah.

25 DR. BOWMAN: It sort of uses the guideline

on talking about the broadcast.

DR. OWEN: Yeah. I mean, really there's a fair amount of -- quite a bit of information already available on, of course, broadcast, and also base stations. And it's really we just don't quite know where to plug into that, these developing technologies --

DR. BOWMAN: Correct.

DR. OWEN: -- and also the realtime use exposures from a wireless phone handset compared to that. I mean, we know when it's held to the head that it's higher than all those --

DR. KHEIFETS: No.

DR. OWEN: -- things. But in the other modes --

DR. KHEIFETS: Yeah, I think that that's --

DR. OWEN: -- we around the table at the moment don't know that.

DR. KHEIFETS: Right. I think that's important to kind of -- because even if it's going to be much longer time period when the phone is on but not used, I think that's a component that we need to know is, what kind of exposures occur at that time sort of on a long-term basis.

DR. OWEN: Um-hmm.

DR. KHEIFETS: And hand-free devices, that might be -- I mean, so that the two modes will -- where are the exposures to the other parts of the body when it's operating, as sort of the same model, just modeling not just the brain but other parts too.

Is that being done at all?

DR. BEARD: Not by the committee that I'm on. But there is, according to some of the members, that Centelac is starting work on something like that.

DR. KHEIFETS: I mean, perhaps if you have a pacemaker or something and you keep your cell phone here --

DR. LOTZ: Yeah.

DR. KHEIFETS: -- and use the earpiece, is there -- is there a model that's being done to --

DR. OWEN: Don't do that. Don't do that. Don't keep your wireless phone in your --

DR. KHEIFETS: No, I --

DR. OWEN: -- breast pocket if you've got a pacemaker.

DR. KHEIFETS: I know. But do people know not to do it? That's one step too far.

DR. OWEN: Yeah. I mean, for instance, the -- if you look at the hand, even with a conventional

wireless phone that's held to the head, of course, the

hand's getting a bunch of the dose too. But my understanding of the current guidelines are that the hand is one -- is -- has the different -- it's not 1.6 for the hand. It's under the extremity, isn't it.

DR. BOWMAN: Right.

DR. BEARD: Right. Also, it's -- as far as the experimental laboratory setup for testing for compliance, the hand isn't even included in the phantom.

DR. OWEN: And that doesn't affect what goes in on the other side at all?

DR. BEARD: From the -- not from the antenna, certainly. But from the body of the phone, it's possible.

DR. OWEN: Um-hmm. Hmm. Well, I'm surprised that there's not anything --

DR. BEARD: It's been replaced by a plexiglass holder.

DR. OWEN: Right. Huh.

DR. BEARD: They just decided it was too complex to try to get some sort of phantom to simulate the hand and the head all at the same time. It's just hard enough to get the head.

DR. OWEN: Well, in general, would that tend to reduce what the head was getting anyway?

DR. BEARD: Yeah.

DR. OWEN: Yeah. So I guess that's why again, you're attuning to worst case scenario. And so leave out the hand, and you're just getting worst case -- a less good case.

DR. BEARD: Yeah. The language worst case even brought up a lot of --

DR. OWEN: Sorry. I didn't mean to get into that.

DR. BEARD: Well, because there's a lot of people from, you know, Asia and other -- all over the world on this committee. And use of the worst case, you know, they thought that should be best case, shouldn't it? Isn't there -- so it was all changed to conservative. The standard now says, everything is conservative.

DR. OWEN: Yeah.

DR. BEARD: There's no best case/worst case.

DR. OWEN: I ran into a similar problem working with the Japanese group, because they said that they could not distinguish between possible and probable.

When I said possible or probable, it was a meaningless distinction to them.

DR. BEARD: Um-hmm. Yeah, it's --

DR. OWEN: And that was really -- and then they asked a group of us to try and define it for them.

And it turned out that there were four of us, and each of us had a different idea of what the definition between possible and probable was. So --

DR. BEARD: It's amazing the semantic problems that come up in these international groups.

DR. OWEN: Yeah.

DR. KHEIFETS: It's like a negative result for biopsies. In some cultures that's -- they think it's really bad news because it's a negative result.

DR. BEARD: Yeah.

DR. OWEN: Untoward result. Is it a good time to kick over into the other things that you suggested, the other ideas about methodological studies? Have we come to kind of an end of the trail for this talk that's just about the exposure assessment?

DR. KHEIFETS: Yeah, I --

DR. OWEN: We can come back if something pops into somebody's head.

DR. KHEIFETS: I don't know. I mean, the -- I mean, I was just trying to be responsive to your chart here, to try to see what sort of specific follow-up could be done for the Muscat study.

And I mean, the one big thing we can't do anything about, which is latency, obviously. So that's

kind of, I think we need to acknowledge up front, you

know, that it is just limited by that and it's never -- you know, there's no way to overcome it, other than repeating the study when the latency has elapsed or, you know, there is more users.

Other than that, I don't know. Is there -- I mean, what are the issues with the Muscat Study? I mean, one is the use of hospital controls. Second is the use of cancer controls for some -- in some centers. They have proxy interviews for the first year of the study, for the 43 cases and 6 controls. They have a very --

DR. BOWMAN: Did they interview proxies for the cases, as well as the controls?

DR. KHEIFETS: They said forty -- they didn't do it for the same case control care. But they just say, for the first year, 43 of the case interviews and six of the controls were conducted with proxies.

And then after that, they were somehow able not to do it, or they stopped --

DR. BOWMAN: They were getting them early enough while they were still --

DR. KHEIFETS: I don't know -- yeah, they still have a refusal, although it's not so bad. I mean, they have -- they claim they have 82 percent of cases and 90 percent of controls. Which I don't know. It seems that if that's the case, that's pretty good.

DR. BOWMAN: Yeah, that's really good.

DR. KHEIFETS: Yeah.

DR. BOWMAN: That is one thing, though. Cancer cases, they go through a phase where they're dying to know a cause for the cancer and would probably be cooperative.

DR. KHEIFETS: Well, yeah. And then the -- then the exposure assessment -- the exposure assessment, of course, is quite good, I guess. They weren't able to access the records. And they just used -- bring two years of information, and they gave some correlations between what people reported and their actual phone use. And if they switched between one provider and another or type of phone, that that correlation goes down substantially, in half basically.

So I don't know. Is this --

DR. OWEN: There was one question that came up in early discussions of the study, long before it was published, keying on the sub-group finding and that -- what was it? -- 30 of the 33 cases were from one of the

five or six centers?

DR. KACZMAREK: Yeah. There's a question about the interpretations from the pathologist in the study. I mean, there may be merit in terms of sub-type analysis and essentially having an expert panel to review

cases, particularly for sub-types where there may be more dispute.

DR. OWEN: Do you mean in future studies or going back at this study --

DR. KACZMAREK: No, in future studies.

DR. OWEN: Oh, okay.

DR. KACZMAREK: In this study again, I mean, there's major limitations, things like duration of use. It's nothing we can do anything about.

DR. KHEIFETS: But would it be worthwhile if that was the main question about the study would be worthwhile? I mean, that's certainly probably something that is quite visible, is have --

DR. BOWMAN: Right.

DR. KHEIFETS: -- blind reclassification of the pathology reports --

DR. KACZMAREK: Right, there may be merit in that as well. Although, again, given the fact I looked at so many sub-types, it's more important to replicate the study and see whether there's an increase again for that particular sub-type and not for other sub-types.

DR. KHEIFETS: And maybe --

DR. KACZMAREK: But that's something that possibly could be done.

25 DR. KHEIFETS: And maybe that could be

done with Inskip's Study too, I mean, just to try to look at them to try to get much more of a -- I mean, one way to look at it, the Inskip Study is a replication of Mus -- I mean --

DR. OWEN: Right.

DR. KHEIFETS: -- you know, is already --

DR. OWEN: I think Peter looks at it that way.

DR. KACZMAREK: Yes. Right.

DR. KHEIFETS: It is a limited attempt to, you know, replicate, you know, with having the same kind of problems, et cetera. So, certainly, I think that would be the other possibility is to try to see whether a common analysis could be developed for the two studies, including, perhaps, a common pathology review --

DR. BEARD: Right.

DR. KHEIFETS: -- that would classify, in both studies, cases the same way, that's blinded to, you know, as much as you would get the pathologist to rely on -- I mean, they don't like to be blinded in anything. But

--

DR. OWEN: Just kind of a side question.

How likely do you think it is that those respective groups would be willing to comply with an attempt to do something like that? Any guess? I mean, I've dealt with people in

--

DR. BOWMAN: Get somebody who --

DR. OWEN: -- animal studies that don't want to give up their slides for path re-analysis.

DR. BOWMAN: Have money and --

DR. OWEN: And beg.

DR. BOWMAN: Right.

DR. OWEN: Okay. Just wondered.

DR. BOWMAN: Money does help.

DR. OWEN: Yeah.

DR. KHEIFETS: I mean, we have done, you know, combined analysis of studies.

DR. OWEN: Right. You can do it short of getting the slides back out. You don't --

DR. KHEIFETS: Well, that was not the issue. I mean, I don't think the slides -- well, I don't know. Why would slides be more of an issue than data in general? Maybe they -- they might not have the slides. I mean, they might just have relied on the hospital diagnosis.

DR. BOWMAN: That's usually --

DR. KHEIFETS: That probably was the case.

So it would be getting confirmation from the hospital.

But people don't like doing that. But you could talk them into it. I mean, it very much depends on the personality.

I mean --

DR. BOWMAN: Yeah. Leeka's had an experience with.

DR. KHEIFETS: Yeah, but only one who hasn't -- I mean, really only one person who --

DR. BOWMAN: Yeah.

DR. KHEIFETS: -- would collaborate.

DR. BOWMAN: Yeah.

DR. KHEIFETS: And then he said that from now on he will always collaborate. He said, now I understand --

DR. OWEN: Got a big enough black eye out of that.

DR. KHEIFETS: No. He said, now I know. Then he gave his, and nobody used it. So it's kind of -- for the childhood studies. That's a little bit embarrassing.

DR. OWEN: You mentioned a few things, Leeka, just when you were --

DR. KHEIFETS: Um-hmm.

DR. OWEN: -- paging through the study, like you mentioned about hospital controls and some cancer controls and the use of proxy interviews. Are any of those things, for which you can think of, studies that

would be useful to address those issues, or those would

just be things that if you did another case control study, you might take a different approach to those issues?

DR. KHEIFETS: Well, let me just -- I mean, I think it's both. Let me just say, sort of up front, that, I mean, once you have the study, all the supplementary studies are going to provide very limited information. You're never going to really be able to -- you could just sort of generate a hypothesis, saying, it's likely that this might have occurred.

For example, you know, the pathologies were probably, you know, not classified correctly, and this might have influenced the results, or something like that. And then in the future, you know, this would be a much better way to categorize and, you know, specify in advance what sub-types you're going to look at and whatever that was.

So, I mean, you know, I don't think -- I don't want -- you know, with a lot of effort, you might not get so much for that effort. But the effort is much more limited than going to a full sort of study, of course.

So, you know, you're just -- you're spending a lot of money, but not huge amount, and you're getting very limited data. So --

DR. OWEN: Okay. Let's go the other

direction and take into account something that we started to say there. Cause we do want to consider not only studies that are published, but studies that are ongoing like the --

DR. KHEIFETS: Yeah.

DR. OWEN: -- Interphone Study. So --

DR. KHEIFETS: But let me just finish with --

DR. OWEN: Oh, I'm sorry. I didn't realize.

DR. KHEIFETS: But I think that there are things that maybe one can do that might be useful just in general, as well. Is that one could collect, I think, a random sample of a similar age or whatever, and try to see how representative those controls are in general, in terms of their phone use.

I mean, that kind of information might be useful in other ways too. But this should be easily collected, the bulk, I would think. Would that be useful, to just try to see whether, you know, the pattern of phone use that was seen in the studies?

DR. KACZMAREK: Well, there's a question whether if you did that study at this point in time, whether the pattern of phone use has changed over time.

DR. KHEIFETS: Yeah. So you have to go

try to get back --

DR. KACZMAREK: Right.

DR. KHEIFETS: -- to that time period. That is very true.

DR. OWEN: Could you get -- could you answer some of that question by comparing the patterns of phone use revealed in the Muscat and Inskip Studies, or is there just --

DR. KHEIFETS: You can. But you have hospital controls in both.

DR. BOWMAN: Right.

DR. KHEIFETS: The question is whether the hospital --

DR. OWEN: Okay. To population rather than hospital. Okay.

DR. KHEIFETS: And it would be useful to even compare the two, just to see, you know, were they the same or not. But the question is, you know, is that a population type of use or not.

DR. OWEN: Okay.

DR. KHEIFETS: So that's something one could do, with the caveat that one has to watch for the time change.

DR. OWEN: And -- or would it -- if you

25 did something like that, where you just decided, okay, I'm

going to compare General Hospital to Hospital -- I mean, general population to hospital controls in the present, rather than --

DR. KHEIFETS: Um-hmm.

DR. OWEN: -- directly trying to compare to those, would that be --

DR. KHEIFETS: That could be --

DR. OWEN: -- answering the same kind of question?

DR. KHEIFETS: Probably. You'll always have a question of participation.

DR. OWEN: Yeah.

DR. KHEIFETS: But, yeah.

DR. OWEN: And would that, if you did that, would that be informative for the design of future studies? Say, you know, telling you whether you should avoid using hospital controls. Or is that just one of these issues that people have an opinion in?

DR. KHEIFETS: I think it would be useful in general to see -- you know, I mean, I think that's a

general methodologic question that would be useful. You could collect other information on that as well.

I mean, people -- there is -- most epidemiologists do not like hospital controls. They're -- there are very strong notable exception. Demetri

Tricopulus (phonetic) loves hospital controls and kind of pushes for that all the time. So -- and with the problems of random digit dialing in the U.S. and the problems of participation getting worse and worse, there are probably going to be more hospital control based studies.

So this would be a useful methodological kind of information in general. You could compare them on phone use. You could also compare them on different characteristics too. So I think that that would be -- that could be done, and that would be useful, I think.

DR. BOWMAN: And the studies take place, for the most part, in different parts of the country. So it should be in those regions, and maybe a few --

DR. KACZMAREK: There could be regional variation in phone use.

DR. BOWMAN: Right. We were talking also about a longitudinal study in the areas where cell phones are penetrating the brain --

DR. KHEIFETS: He suggested -- to get around that, he suggested to use current -- same region current hospital controls. So it doesn't have to be --

DR. BOWMAN: Right.

DR. KHEIFETS: -- a particular region. It

could be just to have a comparison, get hospital controls and then appropriate population group somehow, which is

going to be difficult, and try to compare them.

DR. BOWMAN: Right.

DR. KHEIFETS: Right now, with an assumption that that -- well, the relationship hasn't changed, even though the pattern --

DR. OWEN: Between population and the hospitals?

DR. KHEIFETS: Right.

DR. BOWMAN: Well, I guess I'm sort of completing the methodologic study of hospital controls with the exposure survey questions. And, to some degree, they do overlap. And it might be good -- I think it would be good to use the same cell phone survey instruments for the hospital control study, as for the broader survey. But they don't have to be the same study population.

DR. KHEIFETS: Right.

DR. KACZMAREK: Regarding hospital controls as well, and argument's been advanced that when people develop a condition that requires hospitalization, that may affect their cell phone usage. They may even decide to get a cell phone at that point in time because of their condition. And they use the phone in a different manner. And that would make them different from the general population that hasn't been hospitalized.

25 DR. KHEIFETS: And that's what we would

try to assess, to what extent that's the case.

And the other part -- the other thing, to look at the proxies. I mean, you could do another small methodological study that would compare proxy response to the personal response; again, not necessarily in general population. I mean, we don't have to --

DR. KACZMAREK: And again, that becomes a particular issue for the high-grade gliomas. I mean, when the mortality is relatively rapid and people may lose their mental faculties pretty quickly.

DR. OWEN: Yeah. I guess you don't have any complete assurance that the relationship between a proxy and a primary would be the same for controls as it would be for --

DR. BOWMAN: Right.

DR. OWEN: -- cases.

DR. KHEIFETS: Well --

DR. OWEN: But can you do anything about that?

DR. KHEIFETS: Yeah. Yeah. You would think they would be similar. But, yeah. I mean, you can go and say that the proxy of a case, you know, tries harder, just as a case tries hard the proxy on the case tries harder too. So --

DR. OWEN: Same question as before. Would

that -- would a little methodological study like that have utility that extended beyond sort of, you know, minutia re-analysis of this study? Would it be use --

DR. KHEIFETS: Well, yeah, I think so for the future studies.

DR. OWEN: That's -- yeah.

DR. KHEIFETS: I mean, you're going to -- You know, given that we're studying brain cancer, even -- there's always going to be some population that's not going to be accessible. So I think that that would be much -- very useful.

DR. BOWMAN: Well, there's --

DR. KHEIFETS: It would be more useful in general and for, you know --

DR. OWEN: That's what I was wondering.

DR. KHEIFETS: Yeah, I think it is, because -- I don't know if they say that or not, whether they did the analysis without. But --

DR. BOWMAN: The current way of looking at questions like that is to do side analyses to qualitatively explore the plausibility of is this a factor that would affect your outcome.

One thought that I threw out yesterday, and I -- I can't really vouch for how realistic it is, is

to use basically inference to adjust the outcomes of the

primary analysis based on the epidemiologic study.

The software for doing that is being used a lot. But to what degree it's usable for things like that, I mean, you know, I need to get people that know that area much better than I do. I just, you know, recall setting in when a statistician was talking about the problem of non-compliance in drug trials. And he was saying, it's common knowledge that the dosage for medication is always too high, cause it's based on clinical trials, where, you know, people don't take their pills. And you use that as an inference to adjust for that.

And, you know, it's one thing to do it for, you know, the people that were given pills, and another thing to do it for a comparison population where they weren't given pills at all.

So what's your lack of compliance rate when people didn't even have pills to begin with, that's a matter of a what-if. But you can do that if you have sample data.

So the thought is to look into, at least, the idea that when given an epidemiologic study, then using the inference to see to what degree this would impact the outcome of the primary risk analysis.

25 DR. KHEIFETS: Just going back to Muscat's

Study. In the table two, they give a percentage in controls, whoever use cellular phone. And you can see that the problem with be use of controls. For cancers, the percent was six. For musculoskeletal disorders, it was 24, almost. So there is -- here is a five-fold or whatever, four-fold --

DR. KACZMAREK: Four-fold.
DR. KHEIFETS: -- difference in controls.

So which one of this is correct. I mean, you know, that would make a huge difference. We're talking about small risks, four-fold difference in controls, you know, is everything.

So, you know, the question is -- I mean, it looks like all the other diseases, too, is much higher than it is with cancer cases. So, I mean, that needs to be understood, you know, to see if the study is valid in that way. I mean, but that's going to, you know, show as

a problem.

DR. OWEN: The possible of hospital controls, using hospital controls?

DR. KHEIFETS: Yeah. I mean --

DR. OWEN: So it sounds like any of these would be -- you would want them, any of these sort of methodological studies to be -- sort of have an integrated design with the other exposure assessment work. I guess

that's what you were saying earlier, is that it was kind of bleeding together in your mind.

DR. BOWMAN: Yeah. I mean, I think I'd want to, you know, work on it in more detail before -- cause there's different purposes. But I would think to the extent, say that you're using software-modified phones to collect usage data, you'd want to have a similar protocol with a broad exposure survey, as you would in a methodologic study, to look at differences and, you know, the surrogates or surrogate recall or hospital-based controls.

DR. OWEN: We were talking a little bit yesterday about pediatric questions. We talked about differences that you might find in exposure assessment. Well, we also talked about differences you might find in, you know, base level incidents of various disease and so on.

But right now, in the context of the exposure assessment discussion. I mentioned earlier that it seemed like, you know, you would be looking at most of

these things for a variety of ages, you know, these various parameters --

DR. KHEIFETS: Um-hmm.

DR. OWEN: -- that are going to affect exposure. Do -- and maybe, Brian, you have the best feel

for this; I don't know.

Do we have a real lack of more of the fine level SAR work on, you know, the different head sizes and different tissue distribution that we'd need to have integrated? Is that an unanswerable question, because we don't know the relevant contribution of these different parameters to the total, you know, the peak, or the cumulative does?

DR. BEARD: The question of, you know, using pediatric phantoms, there's been quite a bit. And the decision was, the geometry, when you're in the near field, is so predominant in the SAR, that the size of the head is the biggest factor. And the larger the head, the higher the SAR. So they're just going with an adult head.

DR. BOWMAN: The bigger the head, the higher the SAR?

DR. BEARD: Better coupling you get.

DR. OWEN: Better coupling to the 900 or 18 --

DR. BEARD: Yeah.

DR. OWEN: Well, is that true also for 1800?

DR. BEARD: Yeah.

DR. OWEN: Yeah. Right, cause they're

25 both roughly the size of a rat --

DR. BEARD: Um-hmm.

DR. OWEN: -- which is about regimen for these frequencies.

DR. BEARD: So to be conservative is they decided to say they're going with an adult-sized head phantom.

DR. BOWMAN: What's the wavelength of a cell phone?

DR. OWEN: Well, mostly around 900 or 1800, in those general areas.

DR. BOWMAN: No. That's the frequency. So what's the wavelength?

DR. OWEN: Oh, I'm sorry. The wavelength.

DR. BEARD: Oh, about 35 centimeters --

DR. OWEN: -- centimeters, yeah.

DR. BEARD: -- at 900, and half that.

DR. OWEN: Yes, 15 -- right, cause 2.45 is about resonant for a good size rat. So --

DR. BOWMAN: Um-hmm.

DR. OWEN: Okay. So barely you had --

DR. KHEIFETS: But -- but -- but, nevertheless, I mean, there's always going to be a question of extra sensitivity in childhood, you know, given --

DR. OWEN: Oh, right. That's a --

DR. BEARD: Right. The decision to use the adjust head phantom was based solely on, you know, getting the highest SAR measurement.

DR. OWEN: Right, even --

DR. BEARD: Not on, you know, whether there's a different effect --

DR. OWEN: Sure.

DR. BEARD: -- in different populations.

DR. BOWMAN: Yeah.

DR. OWEN: Well, you can't do that with dosimetry or exposure assessment.

DR. BEARD: Yeah.

DR. OWEN: I know that.

DR. BOWMAN: You're talking.

DR. OWEN: I'm a biotechs man; I know that.

DR. BOWMAN: You're talking. Sell your studies.

DR. OWEN: Yeah. So -- but one thing I was trying to make sure that that decision, that size was the most important parameter, the most influential parameter, however you want to talk about it, that included discussion of, you know, relative size of sub, you know, tissue, different tissues and everything,

right?

Or did it not?

DR. BEARD: I believe it did.

DR. OWEN: The question -- I mean, somebody raised the issue --

DR. BEARD: That was the debate early on in the committee deliberations.

DR. OWEN: Okay.

DR. KHEIFETS: I mean, I know that bone marrow -- I don't know of bone marrow in the skull. But, certainly, bone marrow in the limbs and other places is very different for children than for adults. So --

DR. OWEN: And Camilla Gabriella specifically said something about differences with respect to age, although I think that was based on rat data.

DR. KHEIFETS: So, yeah. I mean, I don't know if -- I mean, I'm not --

DR. BOWMAN: Isn't it Stewart reports arguments about children based on its developing cells and -- now I'm well out of my league.

DR. KHEIFETS: Well, they talked about both --

DR. BOWMAN: Developing -- development in brain tissue in children versus adult.

DR. OWEN: They mention both exposure level questions, but they also sort of threw in the whole

waste bin full of, well, it could be, you know, an

immunological development. It could be neurological development. You know, things are developing during those times. So we don't know what effect it's going to have -- what it might have on development.

DR. BOWMAN: Right.

DR. OWEN: But those -- none of those were based on any mechanistic investigations and suggested the existence of any, though, effect.

DR. BOWMAN: Right. There was precautionary groups of --

DR. OWEN: Yeah. Yeah. I think the closest thing we have is --

DR. BOWMAN: And, you know, we don't know what the effects on developing cells are, but we know they're developing. So --

DR. OWEN: Right, that was the approach. I mean, the only thing we do really know is the studies high level where there's heating involved.

DR. BOWMAN: Right.

DR. OWEN: But that's all different.

DR. KHEIFETS: And there are no childhood studies that anybody ever have done; is that correct?

DR. OWEN: Of RF --

DR. KHEIFETS: Yeah.

DR. OWEN: -- exposures? I think that's

true. Ron, do you recall seeing any?

DR. KACZMAREK: Right. No. For example, the Inskip Study, individuals under the age of 18 were excluded. So --

DR. KHEIFETS: Same for Muscat.

DR. KACZMAREK: -- we have not been including the pediatric population with the current generation of studies. I think there's certainly a need to do that.

DR. BOWMAN: You know, that would be one clear research.

DR. KHEIFETS: Yeah, I think --

DR. KACZMAREK: The research umbrella should not exclude the pediatric population.

DR. BOWMAN: Right.

DR. KACZMAREK: They should include them. People can disagree with that.

DR. BOWMAN: As well, of course, the exposure surveys, we should look at that.

DR. OWEN: And that one is something that's fairly easy to address. If you're doing exposure surveys, you can do those up front with a variety of ages, activities, so on.

DR. KHEIFETS: Um-hmm.

DR. BOWMAN: Just as long as you don't

encourage them to use the cell phone.

DR. OWEN: Yeah. Yeah.

DR. BEARD: Would the endpoints be significantly different for pediatric population? I mean, since you're talking about possible causes here that relate to development as opposed to, you know, strictly cancers.

DR. OWEN: The endpoints for which there's even a hint of mechanistic data, you would say, probably not. Of course, endpoint for which there's no mechanistic data to suspect there's a problem in the first place, you can't say.

If you really wanted to go way, way, way out on a limb, there are some similarities in the carcinogenesis process in this direction, the development process in this direction. So cellular and tissue changes that occur, there are some very, very basic types of changes.

Some people would characterize carcinogenesis as the differentiation of tissue, and sometimes it looks like that. But those are very -- as I said, they're going in opposite directions and they're -- that would be really stretching it. I mean, that would be way out in theoretical biology.

25 DR. BOWMAN: Well, the cancer incidence

data by age that Ron was talking about yesterday, there was a blip --

DR. KHEIFETS: That's what I thought he said too.

DR. BOWMAN: -- for the younger children, then it's low until you get to the older ones, where it goes up exponentially. And that would be some evidence in support of that in the developmental stage, there's a higher susceptibility to cancer than for the mature adult, until the aging process starts accumulating mutations.

DR. KHEIFETS: Say it again. For which outcome there is a hint of --

DR. OWEN: Cancer outcome.

DR. KHEIFETS: -- mechanistic --

DR. OWEN: And as I said yesterday, I think that may be a function only to the effect that most of the cellular research has been cancer focused, you know, looking at --

DR. KHEIFETS: Um-hmm. Um-hmm.

DR. OWEN: -- cancer mechanisms. So I think that may be an artificial focus there.

DR. KHEIFETS: So you are going outside cancers to other --

DR. OWEN: Well, no. I was saying

outside

25 cancers is really, you know, even less. So essentially

nothing.

DR. BOWMAN: Right. So the --

DR. OWEN: Other than the --

DR. BOWMAN: -- most obvious -- the most logical is that children should be included rather than excluded --

DR. OWEN: Oh, yeah.

DR. BOWMAN: -- from the cancer study.

DR. KHEIFETS: Well, you have to do a separate study. You have to do separate studies on --

DR. BOWMAN: Well, it depends on what your -- I mean, the interviewing, obviously, has to be different.

DR. KHEIFETS: Yeah.

DR. BOWMAN: But the case of -- the case accumulation, you're still using tumor registries.

DR. KHEIFETS: Yeah. But it's just there are so many differences. They just have to -- I mean, to get enough numbers, you would have to --

DR. OWEN: You mean just in a logistical -- permanent logistical perspective, and it's just not feasible to try and capture both in a single study design.

DR. KHEIFETS: You just -- you just -- yeah. I mean, usually it just doesn't work out that way.

25 You don't get enough cases if you don't focus on it. And,

you know, you have to involve parents, and it's different. And the questionnaire will be different. There are just enough differences that they --

DR. BOWMAN: I agree.

DR. KHEIFETS: -- usually you would have to do a separate study for children.

DR. KACZMAREK: One issue with a case control study, I mean, basically, you're looking back in time for the exposure. So if you caught cancer, let's say, in the early 20s, it might be plausible there were exposures, basically, in the teenage error.

DR. OWEN: In the early teens, yeah.

DR. KACZMAREK: Right.

DR. KHEIFETS: Um-hmm.

DR. KACZMAREK: So you would actually be able to recruit younger, very young adults.

DR. KHEIFETS: Um-hmm. Um-hmm.

DR. KACZMAREK: But your exposures could be in the pediatric range, and most people can give consent.

DR. KHEIFETS: But they're not -- I mean, there are not a lot of cases, I --

DR. KACZMAREK: No. Right. Collecting the required number of cases --

DR. KHEIFETS: Yeah.

DR. KACZMAREK: -- could be challenging.

DR. KHEIFETS: And, I mean, here they started at 18, for Muscat's Study. But, you know, you're not going to have a lot of cases from 18 to 30, or whatever.

DR. OWEN: Cause even though there's that small peak around, what was it? -- nine or ten, that you were talking about, that peak is still smaller than the one --

DR. BOWMAN: Right.

DR. OWEN: -- that is occurring in the roughly six --

DR. KACZMAREK: Right. I mean, you have tumors in the very young pediatric population that don't occur in the adult population. But the -- there's not much mobile phone use in that particular population.

DR. OWEN: Well, that too, yeah.

DR. KACZMAREK: That's the very low end of the range, obviously.

DR. OWEN: Yeah.

DR. BOWMAN: So maybe that is feasible.

DR. OWEN: Oh, yeah, here's one. This is

-- it was the question, of course, about other endpoints. And, of course, one way to address that is cohort studies. But say, if you're thinking of neurodegenerative disease,

is it true that there aren't registry -- aren't good registries that you could work from for those? You don't --

DR. KHEIFETS: Yeah -- go ahead.

DR. OWEN: You don't have -- the animal data, you're not going to be able to generate animal data on those. No -- it's true that not much is known about the etiology of those in general.

So is there -- is there a way to do -- to find out any information on that, aside from cohort?

DR. KHEIFETS: Well, I mean, it depends which neuro -- I mean, the cohort is not particularly good to do that either.

DR. KACZMAREK: If the outcomes are very rare, obviously, it's going to be --

DR. OWEN: Yeah.

DR. KACZMAREK: -- highly inefficient.

DR. KHEIFETS: Right. But also, the outcome is not well diagnosed. I mean, if it's -- if we're talking about Alzheimer's Disease --

DR. OWEN: Yeah. You can't --

DR. KHEIFETS: -- a lot of it goes undiagnosed and, you know, it just -- you've got that many, it's going to be hard to -- even in the cohort, I

know now immortality is very -- I mean, using death

certificates for that is not a good --

DR. OWEN: Yeah.

DR. KHEIFETS: -- methodology either. So you're not going to get a lot of stuff from that anyway. For the cohort, I think you could -- I don't know. I mean, it just when you get into non-cancer outcomes in general, it's just classification becomes more of an issue. You really have to worry about that. But, you know, if you don't do mortality.

And then if you go to mortality, then you have issues of classification. So, I mean, you could -- you could easily ascertain mortality. That's the only thing in the U.S. that you could --

DR. BOWMAN: Right.

DR. KHEIFETS: -- ascertain well. And then you have an issue of incorrect classification on the death certificate. So it's kind of hard.

DR. KACZMAREK: The issue with Alzheimer's, just by definition, the patient will no longer be a reliable historian. You'll have to go to

proxies by definition.

DR. OWEN: Yeah.

DR. KHEIFETS: Um-hmm.

DR. OWEN: And if it's CJD, you can't even -- you've got to wait for post mortem.

DR. BOWMAN: That would be something that you would approach really in the cohort study. So -- and as we've been saying our primary exposure data, in that case, is recognized. So while doing a definitive neurodegenerative disease with death certificates is, you know, just not there, it is a way of taking a first look at the issue.

DR. KHEIFETS: Yeah.

DR. BOWMAN: The latency is, you know, a huge issue there as well.

DR. KACZMAREK: Right.

DR. KHEIFETS: From animal work, what, you know, what would be the outcomes that would be of most interest? Is there cognitive work that's any other hint?

DR. OWEN: There is, although it's mostly -- I mean, it's acute investigations. You know, there's not really cognitive work with latency effects from animal studies.

DR. KHEIFETS: Are there other hints --

DR. OWEN: There's not animal models --

DR. KHEIFETS: Are there hints from animal -- from acute effect?

DR. OWEN: You mean of the existence of effects, or --

DR. BOWMAN: Yeah. Have people run rats

in mazes with --

DR. OWEN: There have been --

DR. BOWMAN: -- cell phone radiation?

DR. OWEN: -- findings with -- or there have been reports with very debatable findings based on the other available literature. But the main -- the important thing to take home is that there are studies, follow-up studies already being done on those. So within two or three years, we'll --

DR. KHEIFETS: But the question is --

DR. OWEN: -- have more data on those.

DR. KHEIFETS: But the question is, are there any hints there that we might want to test --

DR. OWEN: No, there's -- no, there's not. But that's partly because there aren't -- there aren't good animal models for any of those human neurodegenerative --

DR. KHEIFETS: So then those new studies are not going to be good anyways?

DR. OWEN: Not for these, no. I thought you were --

DR. BOWMAN: But the acute neurological effects, there's no indication of problems?

DR. OWEN: There's ongoing research to address the isolated indications that there might be

effects.

DR. BOWMAN: Right. That's what --

DR. OWEN: It's not even clear that those effects are problems, but --

DR. BOWMAN: Right. And that's clearly different than neurodegenerative.

DR. OWEN: Yeah.

DR. KHEIFETS: No, but I'm just -- I'm just saying that maybe this is one area -- I mean, if we're talking about young children and we're talking about them starting to use cell phones heavily, I mean, maybe there needs to be some test of whether it affects their -- some cognitive function, I mean that kind of warps, as you say --

DR. KACZMAREK: Right.

DR. OWEN: Yeah. Actually, in the study, the program for which funding has just been announced in the U.K., because of the Stewart Report and other things leading up to it, there's been a, at least discussed, in emphasis, on the non-cancer endpoints, the acute cognitive function studies and so on.

So there's a reasonable anticipation that that program, which is about 15 million dollars, will yield some useful data on those questions. But again,

those are the more acute cognitive function questions.

DR. KHEIFETS: Well, you know --

DR. KACZMAREK: Which are probably best studied in the laboratory setting.

DR. OWEN: Yes. Yeah, laboratory studies.

DR. KHEIFETS: Yeah, that's all right. I mean, that's still human laboratory studies?

DR. KACZMAREK: Right. Exactly.
DR. OWEN: Right. Yeah, right.

DR. KACZMAREK: Yes, right. Right.

DR. KHEIFETS: So I think --

DR. OWEN: Potentially with pediatric subjects, I'm not sure about that.

DR. KHEIFETS: So, I mean, I think that's something that might be worthwhile. I mean, just doing it in one place is probably not good anyway. So maybe you want to have a similar exposure somewhere else too, just a better strategy.

DR. OWEN: One of the other gaps that we talked a little bit about, or a fair amount about, was the limited RF exposures of this particular population and what was the feasibility of identifying other more highly exposed populations, either, you know, mostly by virtue of occupational exposures. And that goes two directions; not only from conventional wireless phone handsets, but also

from RF sources.

And while we talked about it some yesterday, just in quickly looking back at my notes, I didn't feel like we got any definite feelings for whether -- where that was. And it might have been partly because there were some questions raised about needing to find out a little bit more about what's currently going on in some other places.

DR. KHEIFETS: Well, I thought that the main difficulty was that we don't know how to identify a cohort, that a lot of those workers are transient, small operation kind of business, we thought, and that it would be hard to identify that cohort. And so there are two --

DR. OWEN: So it's a feasibility problem more than it's a --

DR. KHEIFETS: It's a feasibility. So one is to really find out -- finding out whether there are union records or any other ways to identify a cohort, or some -- maybe somebody is keeping records. Or if there are enough of these occupations out there, you could do, you know, population-based case control study, where you try to over sample on certain occupations and emphasize. You know, try to really look at occupational RF exposures.

DR. BOWMAN: My recollection of the study,

I could recall three targets seemed to me to have some feasibility. One is the military. We sort of brought it

up and then kicked it aside, because that's not directly within the scope of CRADA. And, you know, the politics of that -- I'm not going to --

DR. OWEN: They can play together.

DR. BOWMAN: You can go there. But if we're making a list of cohort possibilities, that's the one industry-wide study that has, you know, feasibility. The other two were directly related to CRADA. One was the marketing people for the cell phone companies. And, lastly, it is the maintenance contractors for the towers.

DR. OWEN: Yeah. And it seem -- I think I recall there was some mention of the concept on those last two, essentially establishing a little within a company registry.

DR. BOWMAN: Right, as well as back in the dark with exposure measurements. The -- and what we've talked about, both in terms of software-modified phones for the marketing people, and also for the maintenance people. I'm sure they could well be using cell phones, and working and distributing registrations.

But also, the NARDA dosimeter might, you know, be something to look at.

DR. LOTZ: That's actually a place that we

have plans to look at it, and it's -- hopefully with the

tower maintenance people.

DR. BOWMAN: Right. And again, since they are, presumably, contractors to the CTIA members, they're -- you know, there could well be sort of reasonable leverage applied there.

DR. OWEN: Let's talk a little bit more about the potential for finding out things from the military people. I mean, that's not a very specific thing. What kind of things are you thinking of, when you're talking about that? Are you thinking of, you know, just sort of cohort studies within the military? Or are you thinking mostly about the exposure assessment? And do you have a similar approach, where you've got a registry with exposure assessment? Or what kind of things are in mind?

DR. KHEIFETS: Don't they have any study going? I'm trying to remember. I thought Mike Murphy was saying that they are either considering or planning or doing, or something like that, a cohort study. Am I wrong?

DR. LOTZ: I don't --

DR. KHEIFETS: Maybe he was just saying planning, and I was kind of --

DR. LOTZ: Maybe so. I wasn't aware. But I haven't been in close touch with them that much to know

whether they are actually seriously --

DR. KHEIFETS: -- considering that.

DR. LOTZ: -- you know, undertaking.

DR. KHEIFETS: Uh-huh.

DR. LOTZ: You know, the reason they come up is because they have so many people involved with radar, whether as maintenance technicians or whatever. NIOSH set out to do a study with the Army a few years ago that was designed to look at lead exposure in artillerymen. And it turned out, the RF exposure was a substantial confounder that had a greater effect.

DR. BOWMAN: Well, didn't they actually choose the signal corps units as their control?

DR. LOTZ: That was what happened, was they chose the signal corps unit as their control, and found a greater effect --

DR. KHEIFETS: Oh, yeah.

DR. LOTZ: -- on male reproductive endpoints in the radar exposed signalmen, who were to be the control, than they found in the lead exposed

artillerymen.

So they then repeated it with yet a different control population. But that was sort of how it came up.

So anyway, the military has populations or

subsets of people out there who are regularly working around RF sources. And that's why they're a kind of an obvious group. It's not particularly easy to characterize their exposure, because it depends a lot on exactly what tasks their doing, where they're located, what the transmitters are like. And they have a -- even though they have some -- on the one hand, you might think it a sort of a more confined variety of transmitters. There's still a fairly wide array of frequencies and modulations and things like that.

DR. BOWMAN: But still it overcomes the problems that we've been talking about earlier, is that you've got a lot of people exposed to RF in a fairly well defined band width, and they all work for the same employer.

DR. LOTZ: Yeah.

DR. OWEN: All right. Compared to the general population, they're easier to identify, assemble, and track you mean?

DR. BOWMAN: Right.

DR. LOTZ: Rights, definitely.

DR. KHEIFETS: But --

DR. BOWMAN: Exposure assessment is still going to be a challenge. That is more a definable

problem.

DR. KHEIFETS: But don't they leave early on in their career? I mean, isn't that the problem that they just there maybe only as young men, and then you -- the rest, you know, you get them doing all kinds of other things, and you'll introduce a lot of new classifications?

DR. LOTZ: It depends on the sub-specialty they're in.

DR. KHEIFETS: Some of them are long-term.

DR. LOTZ: I mean, they might end up being a supervisor of five other technicians, instead of being the technician --

DR. KHEIFETS: Yeah. Well, that's what -- right.

DR. LOTZ: -- themselves. But they're still going to be there. Now, you have a lot of attrition. I for -- I don't know what the retention rate in the military is with, say, you know, young technicians at this point. It might be only half or something. So you're going to lose people.

DR. KHEIFETS: Um-hmm. Um-hmm.

DR. LOTZ: But, nevertheless --

DR. KHEIFETS: -- there would be some.

DR. LOTZ: And there will be some that move out into other jobs. But there will be a fair

amount

25 that stay in that rate, that expert area for at least

ten

years.

DR. KHEIFETS: Um-hmm.

DR. BOWMAN: And, clearly, if you're looking for shorter term effects, you're going to have better luck than you would in cancer.

DR. OWEN: So far we don't -- we haven't, yeah, worried too much about those.

DR. KHEIFETS: Do they use a lot of cell phones in the military now?

DR. LOTZ: I don't know if they do. I don't know.

DR. BOWMAN: They have so many other forms of wireless communication --

DR. OWEN: Actually, I was just reading something in -- well, it's not a very reliable source. But it was saying that they basically gave the contract to the failed Irridium (phonetic), and that Irridium had been retained and was put on a contract to provide military communications and satellite phones, a satellite base. You know, they didn't do so well in the open --

DR. LOTZ: -- commercially, yeah.

DR. OWEN: -- commercially. But again, this source was maybe not a good one.

DR. LOTZ: I -- you know, my suspicion is

that for, you know, that in a way, they're probably not as

-- use cell phones as much as -- or more, certainly not more than any other business.

DR. KHEIFETS: Um-hmm.

DR. LOTZ: Because if they're out in the field and they're really doing military operations, they're probably going to want more controlled access.

DR. OWEN: They also have greater access than most other segments to --

DR. LOTZ: -- to other wireless --

DR. OWEN: -- other wireless devices.

DR. BEARD: And you probably won't see any difference in individual use, private use of cell phones. I mean, they'll use it, but not as part of a military operation. I mean, they couldn't count on using cell phones in that case.

DR. OWEN: Right.

DR. BOWMAN: How much work has the military historically done on the SAR with communication devices?

DR. LOTZ: It depends. Certain systems a

great deal. In fact, they've been pioneering, in some ways, of the SAR, you know, modeling and stuff like that.

DR. BOWMAN: Um-hmm.

DR. LOTZ: In other systems, I think it might vary. But I think there's a fair amount.

DR. OWEN: It seems like they've done more than that, though.

DR. LOTZ: Certainly in some cases, though, they would rely on the things like the dosimetry handbook that they put together for a given frequency, as opposed to having done something specific for that source.

DR. BOWMAN: But they would routinely --
DR. LOTZ: But nevertheless --

DR. BOWMAN: -- put in their specs for a communication device that would comply with --

DR. LOTZ: Yeah, they definitely take a very strict approach to trying to comply. And they have recently reaffirmed, but over many years, formally followed the IEEE guidelines. So --

DR. OWEN: It grew out of military guidelines to start with, right? Weren't they initially developed as part of an inter --

DR. LOTZ: Well, the military's always been involved. But I think probably the first definition of any kind was the 66 ANCI guidelines. So --

DR. OWEN: Okay. A little history I read that traced it through --

DR. LOTZ: Well, there was the whole research effort in the '50s, and '60s, was military based --

DR. OWEN: Yeah.

DR. LOTZ: -- although, it was called the Tri-Service Project.

DR. OWEN: Yeah.

DR. LOTZ: So I don't know. You know, depending on your perspective whether you said they were military or just -- but the first actual, I think definition of them, came out of ANCI. Even then, the people attending the meeting were probably predominantly military, but --

DR. OWEN: Oh, yeah.

DR. LOTZ: Or military subcontractors.

DR. OWEN: Okay. Let's take a break. We'll see if everybody's ready to go again in 15 minutes.

(BREAK - 9:59 to 10:26)

DR. OWEN: Let's get back on the road. What I'd like to start with is that I received a letter, and I now understand that the intent was that I would share this letter with the people at this meeting. And so I'll pass it around. Everybody can take a copy.

It's from a Dr. Stampfer, who, as you'll see when you read the letter, that he has prepared a review of epi and related evidence at the request of Verizon, for -- as input to this meeting. And having read this myself, it's a nice and brief review of several

studies, then with a sort of paragraph of conclusion on the end.

I guess if you want, you can skim this quickly and tell me if you think that any discussion of it is warranted.

(GROUP REVIEWS LETTER)

DR. OWEN: I don't think we're obliged to discuss this or comment on it. But if it's stimulated any thoughts, so that anybody wants to volunteer, I'll be glad to hear it.

As I said, I think, you know, it's pretty much a not-surprising brief review of each of several studies, and then there's an opinion paragraph, or summary paragraph tacked on to the end.

DR. KHEIFETS: It's not unlike what we've said here.

DR. LOTZ: I have one just kind of, almost curiosity question. He says at the top of the third page, in talking of the Johansen Study, that suspected differences such as higher SES among those who own cell phones do not appear to be related to brain cancer. I thought we were saying yesterday that SES is related to brain cancer, or that there are some inverse, actually inverse --

DR. OWEN: Yeah, I think --

DR. KACZMAREK: Yeah, it's been raised at times, right, that higher SES is actually associated with brain cancer.

DR. OWEN: So, yeah, rather than -- I guess he's saying non-relation, rather than characterizing it --

DR. LOTZ: Yeah.

DR. OWEN: -- as a negative relationship.

DR. LOTZ: Right.

DR. KACZMAREK: One thing that's absent in terms of his review of the Johansen Study, he doesn't talk about the potential for exposure misclassification based upon how exposure was assigned to the context of the study, being solely about -- based solely upon subscriber lists and no interviews of actually study participants.

And, again, what we discussed yesterday, that there's clear potential for the phone to be used by more than one individual.

DR. KHEIFETS: I mean, misclassification is clearly present in all the studies and to -- to an extent.

DR. KACZMAREK: He also doesn't mention the mean duration of use in the Johansen Study, which is extraordinarily brief, 3.1 years overall and only 1.9

years for digital users.

DR. OWEN: Yeah.

DR. KACZMAREK: That's lacking as well, in terms of this particular review. But I think that's consistent in his review, just glancing at it very quickly, throughout the studies. You know, as we discussed earlier, Muscat, 2.7, and, you know, less than three years for both cases and controls. And that's absent in this particular review as well.

Also, the Inskip Study, again the mean duration is just about three years, and it's absent from this particular review.

DR. OWEN: Yeah. Actually, in his conclusion paragraph, I think it is, he acknowledges the short lengths, I believe, but then --

DR. KHEIFETS: Um-hmm.

DR. OWEN: Yes. Convincingly, null short and medium term cannot, by themselves, rule out a long-term effect. And then he goes beyond that.

DR. KACZMAREK: Yeah. There's sort of a lack of --

DR. OWEN: Further than I would go.

DR. KACZMAREK: -- a lack of internal consistency, where he readily concedes that for some causes of cancer, a long latency period, perhaps decades, is needed to observe the full effect. And then he's

willing to make inferences on the absence of a long-term effect, without long-term data in humans.

DR. OWEN: Yeah.

DR. LOTZ: Actually, and what surprises me is he's making more than inferences.

DR. KACZMAREK: He's making conclusions. Forget about inferences. I mean, in his exact words, it reads --

DR. LOTZ: It's pretty decisive.

DR. KACZMAREK: -- a long-term adverse affect, a remote possibility. That's basically what he said, without any long-term evidence in humans.

DR. OWEN: But having said all of that, it's an appropriate input for this meeting, and I wanted to share it with you all.

Now, if that's -- unless there's more discussion of that people want to have, what I thought was --

DR. BOWMAN: I guess --

DR. OWEN: Pardon?

DR. BOWMAN: Not being that familiar with the rest of the literature, was his characterization of the rest of the literature being -- despite the lack of biologic plausibility to support a causal link later on in the conclusion of, lack of any persuasive evidence from

laboratory studies. I mean, it's not persuasive, that's for sure. But, you know, again, it's the lack of evidence being --

DR. LOTZ: I would -- you know, Russ said he'd characterize things differently. I think there is a difficulty in plausibility for the -- for long-term low-level effect, that we don't have --

DR. BOWMAN: Right.

DR. LOTZ: -- we don't have it demonstrated.

DR. OWEN: And we do have to acknowledge that fair amount of studies had been done --

DR. LOTZ: Yeah.

DR. OWEN: -- looking for --

DR. LOTZ: Yeah. For example, most of the general tox work is negative.

DR. KACZMAREK: We don't have an established, recognized mechanism for the effect.

DR. LOTZ: Yeah. Right.

DR. KACZMAREK: I think we can all agree

on that.

DR. LOTZ: But the, you know, the -- I would not make nearly so much of the negative long-term animal studies as he does, because they're very limited in -- there aren't any, at least I don't think any of the

negative ones, who actually use more than one dose, and oftentimes, it is an extremely small -- low dose.

DR. BOWMAN: Right. We were talking about it --

DR. LOTZ: So that just, it leaves you with a number -- you could count up the number of papers that have a negative answer. But I don't think they're as conclusive as, you know, might be otherwise interpreted.

DR. OWEN: Yeah. I mean, there's clearly still a strong need for the long-term animal study data that's not been addressed by studies that have been done thus far.

Of course, it remains to be seen whether the collection of studies that are just beginning right now in the framework, will address those needs or not.

DR. LOTZ: Yeah, that's right. There may be things in progress that will do better. Leeka's comment yesterday, I think you said something --

DR. KHEIFETS: Yeah.

DR. LOTZ: -- about the lack of meaning

out of negative animal studies.

DR. KHEIFETS: What's the current thinking on the brain tumor models? I mean, it's not very good models, right, for --

DR. OWEN: No. In fact, that was,

actually, probably the most important thing about that study was its work in -- I mean, in some ways, in terms of trying to do a better job of setting up a model.

DR. LOTZ: Which?

DR. OWEN: The 80.

DR. LOTZ: Oh, yes. Right.

DR. OWEN: Because there's not a developed model for brain cancer. But the flip side to consider there is that it's not really that typical to depend upon a rodent, specific rodent model, of a particular human disease, in order to do --

DR. KHEIFETS: Yeah. Right.

DR. OWEN: -- general tox --

DR. KHEIFETS: Right.

DR. OWEN: -- analyses.

DR. LOTZ: And that's an element in terms of the plausibility question.

DR. KHEIFETS: Yeah.

DR. LOTZ: If there were a

demonstration
-- well, you know, the couple of studies that are positive, like the Repitroli Study with the pin-one mouse.
Yeah, you can argue a lot whether about there's, you know, merit in the pin-one mouse, whether the model was used appropriately.
But if that finding were to be

substantiated in another study, it would certainly raise the plausibility question a great deal.

DR. KHEIFETS: Um-hmm.

DR. OWEN: Most people -- most cancer biologists, at least, would not question at all the plausibility -- that that might lend plausibility to a brain cancer, or any cancer effect. It's just -- they're not usually -- those monitoring systems are usually not used to screen specific human diseases.

The disease specific models are more used to learn about specific mechanisms and actually to investigate more, you know, therapeutic approaches, not as hazard identification tools or screens.

DR. BOWMAN: Thank you for sharing.

DR. OWEN: Well, I was getting ready to pick on you anyway, cause you mentioned --

DR. BOWMAN: Okay.

DR. OWEN: -- yesterday wanting to discuss a prioritized list. I think you said something in

particular about being willing create a prioritized list or something like that.

DR. BOWMAN: That would be what I would want to review, rather than the transcript. Let me clarify.

DR. OWEN: Oh, okay.

DR. BOWMAN: But if you would like to use group time to discuss prioritization, I'd be --

DR. OWEN: That would be fine. I think that we could talk about that a little bit. You know, I was --

DR. KHEIFETS: That was the prioritization list. You erased it.

DR. LOTZ: I was looking for it too, Leeka. I was like, wait a minute. It's gone.

DR. KHEIFETS: Exposure assessment, three times.

DR. OWEN: Yeah. Well, that was -- the main message of that was, yeah, the exposure assessment was at the top. And I put it three times, cause that was the, I thought, the pretty clear message in terms of priority, in almost a combined priority, feasibility analysis. It's not only something that's at the top of the list in terms of the unanswered needs, but it's also something that a lot of people think can and should be addressed.

DR. KHEIFETS: Um-hmm.

DR. OWEN: There's no reason to wait to address those questions.

DR. LOTZ: And, in fact, we've talked about it before. But as Joe mentioned, the priority of

the feasibility, but also the sort of connectedness to the Interphone Study. If we have the exposure assessment data on U.S. population, even if we have no component of the Interphone Study, it would help us to relate to the findings of the Interphone Study in terms of the specific.

DR. OWEN: Right. I mean, it would be -- potentially, you could -- one could be finished collecting the exposure assessment stuff by the time you got the results of the --

DR. BOWMAN: Oh, yeah.

DR. OWEN: -- rest of the Interphone Study.

DR. BOWMAN: If you couldn't, you're not trying very hard or there's some sand in the mechanism.

DR. KHEIFETS: Is there a need for any instrument development that we haven't discussed? I mean, is this new, is the dos phone, and whatever the new NARDA interest -- instrument is, is that the sufficient --

DR. LOTZ: I don't think that's the end of the line. I think those are along -- those are some recent breakthroughs that make it even more valuable to undertake such studies. But I wouldn't think that they're the end of the line. I -- partly because they're both

such brand new instruments, I can't believe that we won't find some things as we begin to use them, that couldn't be

-- couldn't progress. You know, it'd be sort of like when the first M-dex came out, that wasn't the end of the line in what you want to do.

So there may be some work there.

DR. OWEN: And I don't remember if you were in the room. I know you were gone from the room briefly this morning where we talked about, perhaps doing some environmental measurements that you need to do before you want to design a next generation personal dosimeter type things to look at RF exposures.

Now, where that might fit in, in a priority scheme --

DR. KHEIFETS: Well, I mean, I think -- I don't know about priority as well. But I think that in the way we -- or in way you could write this up, is just to say that, you know, after today, there's limited personal exposure information that's available for any population. Then develop the meters, so, you know, give an opportunity to really put together a baseline or some sort of information that will be very valuable, and not

waist your time to do that. Then we have the meters; and I think that that's -- and that would lead to a much better understanding of what the priorities are, after we have a little bit more of the data.

DR. OWEN: And clearly, with the dos phone

and even with the other less sophisticated software-modified phones, we've said repeatedly that we see a huge potential for expanding our exposure assessment knowledge using those.

DR. KHEIFETS: Um-hmm.

DR. OWEN: Let's see. We talked a little bit about the possibility of using other registries to look for things. And that was an idea that I just mentioned because it had come out in an earlier meeting. And I think we've fairly thoroughly covered that that was a low-yield approach in the current scenario, current situation.

If you take into account the type of endpoints and whether there are additional registries to use, if I understood the discussion yesterday correctly, we talked about -- I'm not sure we got -- we talked about a continuum of possibilities for case control studies.

I think we only talked in any depth about case control study. We talked about in terms of case control -- clearly, there's the potential for learning a

lot by doing additional case control studies that are even, you know, essentially include replications of the existing case control studies or, you know, case control studies looking at the endpoints that have been identified, based on head and neck tumors, focused that

way because of, at least our current perception, that that's where the highest exposures are tissue-wise.

And that was kind of at one extreme. But we also talked about sort of the other extreme being some sort of pooled or other combined analysis of the Muscat data and the Inskip data.

DR. KACZMAREK: Regarding new studies though, it's not just the function of improved exposure assessment, although that's intrinsically desirable. But if you do the studies now, or essentially they won't be done tomorrow, it will be done later in time, those studies, obviously, will have far greater potential to have study participants with a far greater mean duration of use, which I think is a crucial variable.

DR. KHEIFETS: Um-hmm.

DR. KACZMAREK: So I think that's a compelling argument to do studies in the future. It would be far easier for those studies, again, for the study part disciplines to have substantially greater mean durations of use.

DR. OWEN: And probably the -- my understanding is that the Interphone Study will sort of hit that -- help address that in a double-barrel fashion. Not only is it being conducted a few years later, but also is being conducted on collection of populations that, at

least anecdotally, are much higher users, you know, higher market penetration of technology and perhaps higher use by those people who have phones.

DR. KACZMAREK: But I think as we have discussed, there's still a -- it's still desirable to obtain U.S. data in addition to that.

DR. OWEN: Right.

DR. KHEIFETS: And not only that. I mean, I just, you know, people shouldn't -- I mean, it's very tempting. It's a huge effort. It's a lot of money. And so it's tempting to kind of think of it as something that's going to answer all the questions; but it's not.

I mean, it's not -- it, you know -- and so it's going to be multi-center. There are going to be all kinds of differences between the centers. Each center might not be large enough to really answer the questions. So you're going to have all, you know, kind of findings that are not necessarily going to be definitive.

And so it just, you know -- I just always worry about expectation that somehow this study or that

study is going to be the end-all to all the studies and somehow magically will answer all the questions. It's just -- it's not going to happen, so -- there's always good prudent to, you know, plan ahead and try to think what -- how to improve --

DR. OWEN: Well, that actually brings me to the question I was going to ask is, is it possible to answer this question? Would it be more valuable to have a U.S. group doing an Interphone-type study contemporary with the Interphone? Or would it be potentially more valuable to wait and do that, you know, five years offset into the future? Because you would learn from the shortcomings of whatever wasn't optimal in the Interphone Study, and because you would capture, again, the things that Ron were saying, you know, higher market penetration and higher degree of use and so on. So it's a little bit of the latency question.

I don't know if you can answer that question, which is better.

DR. KHEIFETS: Well, we could talk about it. I don't know if we can answer it.

DR. KACZMAREK: Right.

DR. KHEIFETS: We could answer it. But how close to the truth we would be, I don't know.

You know, I mean, first of all, I think we are off already. So, you know, there's no way to catch up. I mean, we would -- maybe we're not off five years, but we are off two years or three years --

DR. BOWMAN: Right.

DR. KHEIFETS: -- anyway. So we are off.

You know, if you are part of a large study, it has advantages, because the small number of sub-group analysis, a lot of things become more feasible.

On the other hand you certainly -- we will certainly learn some things from the Interphone Study that might be, you know, be in better position to follow-up. So I --

DR. BOWMAN: A sequel to Interphone, say in five years, from my point of view, has some merit in terms of latency. If we're talking 10, 15 years latency, even the Interphone Study really won't have a lot of people --

DR. KHEIFETS: Oh, yeah.

DR. BOWMAN: -- that had had that length of exposure or that much time after significant exposure. So an Interphone sequel, in say five years, could help. As I was saying yesterday, I would hope it would include some of the dosimeters that were in the present Interphone. So that you could not only include U.S. centers, but also be able to --

DR. OWEN: Have a longitudinal view.

DR. BOWMAN: Yeah, have a longitudinal prospect.

DR. KHEIFETS: But also, I think with the issues on exposure assessment that we've talked about, if

you start now, you know, you hardly would be ready in three years to start a study. And you will be five years old from the Interphone Study anyways. Because, by the time, I mean, you answer all those questions and collect the information, which would be useful to plan a study in the U.S., and then the longer you wait, the more information you're going to lose about what's going on today, and not have that baseline information and not being able to then estimate exposure well into the past.

I mean, so I think the plan is kind of coherent. I don't think there's an issue.

DR. KACZMAREK: It's a question of relative duration of use as well. Even though Inskip and Muscat published in the last several months, the data collection and the exposures and case recruitment took back -- took place further back in time. So there could be a very substantial difference for a study that was even -- where the planning began today --

DR. KHEIFETS: Um-hmm.

DR. KACZMAREK: Recognizing the study

won't actually be conducted for some point in the future. -- between that, the mean duration of use, and the participants in that study, as opposed to Muscat and Inskip.

DR. OWEN: Yeah. Yeah, cause when you're

-- if you're focusing on a latency question and you're looking at U.S. use, you know, right now if about a third of the population subscribes to phones and then, you know, out of those are the, you know, make up a number that -- you know, I don't know what percentage of those use the phone for more than five minutes a day.

DR. BOWMAN: Well, we've got the --

DR. OWEN: Yeah. I don't remember what the number is there.

DR. BOWMAN: Right. But it's not that large. I mean --

DR. OWEN: Yeah. And so even if you were sort of starting your --

DR. BOWMAN: No use is like 600, and some use is more like 150.

DR. OWEN: It was in the -- yeah. So even if you were starting the, you know, to try and study the effects of the exposures that are beginning now, then, you know, there's a significant period of time for anything that has any latency at all.

DR. KHEIFETS: Yeah. The Muscat Study from '94 to '98. Under the best of circumstances, you wouldn't start recruiting cases before 2004, probably. So that's ten years difference.

DR. OWEN: Yeah.

DR. KHEIFETS: So that's a reasonable difference.

DR. OWEN: Yeah, that's true.

DR. BOWMAN: It's really sort of striking in my outlook now on the case control versus the cohort. In especially comparing it to the previous meeting that was so heavy in favor of the cohort, is that the question of getting additional exposure data beyond the billing records that can apply to the whole cohort, still leaves it fairly flat in terms of exposure assessment, with not knowing even the make of phone. It means that there's an awful lot of uncertainty as to exactly what the exposure will be for the individual.

DR. KHEIFETS: So, I mean, I think that are recommendation was that if cohort study were to be undertaken, it needs to be heavily subsidized by exposure assessment, embedded exposure assessment, you know, throughout the study that would enhance --

DR. OWEN: -- beyond the billing records.

DR. KHEIFETS: -- beyond the co -- yeah, beyond the --

DR. KACZMAREK: I mean, it may not be a case of either/or, either. I mean, it's not choosing between the two. I think in an ideal situation, you'd be

able to pursue both avenues.

DR. OWEN: Which both avenues?

DR. KACZMAREK: Be able to perform --

DR. KHEIFETS: Cohort and --

DR. KACZMAREK: -- case control studies, as well as a cohort, as opposed to making a choice, saying we're only going to go case control or we're only going to have a cohort.

DR. KHEIFETS: Um-hmm.

DR. KACZMAREK: I think, clearly, the ideal approach is to pursue both avenues?

DR. BOWMAN: Yeah. Using the suggestion that you donate two pennies per bill rather than a penny, they can do both.

DR. KHEIFETS: It's easy --

DR. OWEN: I'm at a loss to --

DR. KHEIFETS: -- to spend somebody else's money.

DR. OWEN: I'm at a loss to think of what we need to discuss more right now.

DR. KACZMAREK: Just one other comment too, about the relative mortality of the conditions. Again, if you're focusing on prioritization, I think it's not an unreasonable principle to focus on the most lethal conditions, conditions with greater mortality rates. And

again, basically, that gives greater prior to a study of

gliomas, as opposed to acoustic neuromas. In fact, you know, that choice has to be made.

DR. OWEN: Um-hmm.

DR. KACZMAREK: I think that's a reasonable basis for making it, or at least contributing to the final decision.

DR. KHEIFETS: The other group, did they discuss the childhood, possibilities for childhood study?

DR. LOTZ: There was a -- there was a brief discussion of it. Actually, there was someone from the general public who was there and who stood up and advocated that there ought to be an emphasis on studying, particularly adolescents, say.

And I think the feeling of the group was that that would be much more difficult with less likely -- that certainly didn't -- ran into problems, even greater problems with latency --

DR. KHEIFETS: Um-hmm.

DR. LOTZ: -- if, in fact, we're talking about brain cancer, for example, as a primary concern, and that they would feel it more profitable to study an older cohort rather than the younger one.

DR. OWEN: Yeah, there were a couple --

DR. BOWMAN: What was the latency

argument

again?

DR. LOTZ: That if --

DR. KHEIFETS: There are not enough kids yet using the phone.

DR. LOTZ: There are not enough kids using. And if you're talking about having to follow them for ten years or more, just to begin -- because of latency, to see the disease show up, that there might -- and there's a higher incidence of cases in an older population, that -- say 30 to 40, 50-year-olds, that it'd be more valuable in the study -- you'd have more ability to build a study that you could detect the difference in, if you studied that adult population, rather than starting with the younger ones.

I don't -- Russ, if I'm expressing --

DR. OWEN: Yeah, there was definitely a --

DR. BOWMAN: The reason I'm questioning that is that --

DR. KHEIFETS: -- latency should be shorter.

DR. BOWMAN: Right.

DR. KHEIFETS: Yeah. No, I think so too.

DR. KACZMAREK: Well, if you go case

control, it's actually not an issue at all.

DR. KHEIFETS: Right, that's true. That's true.

DR. KACZMAREK: I mean, you can collect cases of individuals with cancer in their 20s. I mean --

DR. OWEN: Yeah, there was very little discussion of the case control in that group. And certain -- I don't think there was any discussion of pediatric approach case control.

DR. LOTZ: No, there was no discussion of pediatric case control study.

DR. OWEN: There was the discussion of tuning a cohort study to the 30 to 50, or 40 to 50, or 40 to 60, some age range like that -- I can't remember precisely what it was. -- because of the --

DR. KACZMAREK: The baseline incidents of cancer is going to be greater in that nature.

DR. OWEN: -- because of the baseline.

DR. LOTZ: That's right. That was the rationale.

DR. OWEN: Right, as, of course, predicated on some substance. There was also concerns expressed that it might be even more difficult to maintain, you know, to retain subjects in the cohort who came in as adolescent, or, you know, as children --

DR. LOTZ: Yeah.

DR. OWEN: -- and that they'd just be

harder to track, harder to keep track of, and just they'd

disappear through the cracks quicker.

DR. LOTZ: Yeah.

DR. KHEIFETS: So maybe you do a cohort of adults and case control study of children.

DR. KACZMAREK: Case control -- right.

DR. OWEN: One thing that was discussed extensively because there was basically a proponent there, was the use of a web-based interactive survey instrument for a cohort study.

DR. KACZMAREK: It's still people volunteering into the study, though, how representative your sample's going to be. It's a general principle. You want to go out and recruit your study subjects to an established protocol, not allow people to just randomly volunteer. You'll run into major problems with representativeness.

DR. LOTZ: Well, in fact, that -- the proponent of that approach was definitely advocating recruitment through volunteers --

DR. OWEN: Targeting recruitment.

DR. LOTZ: -- through advertising the passive recruitment. Using that and biasing it toward those who would enter through a responding to a web-based approach, so that you then would anticipate you could follow them.

DR. OWEN: Be more likely to retain them, because you had sort of pre-selected for the ones that were --

DR. KHEIFETS: Um-hmm.

DR. OWEN: -- you know, technophallic to start with.

DR. BOWMAN: What else would you pre-select for?

DR. OWEN: Yes.

DR. KACZMAREK: How representative this group would be, would be subject to question.

DR. OWEN: It was interesting, there was also discussion of using that kind of approach to select for a cohort that was enriched in the higher users somehow, you know, by going through, not unions -- well, maybe unions and associations --

DR. LOTZ: Well, we talked about --

DR. OWEN: I think the --

DR. LOTZ: We talked about --

DR. OWEN: -- Realty Association was

mentioned.

DR. LOTZ: We talked about occupational groups in the same sense. And then it followed that there might be web-based ways to recruit that group preferentially. You know, they've got, you know, a home

page, an industry association, those kinds of things.

DR. OWEN: The Real --

DR. LOTZ: But I think that was mostly in the sense of the same occupational type of discussion we've had of, this is where you find the heaviest users in these jobs.

DR. BOWMAN: I could be a little more excited about if there was an industry association that had an email mailing list, soliciting participation through the email linked to a web site for enrollment.

DR. OWEN: One of the reasons that I --

DR. LOTZ: Sort of in the case of that dialing the extension using that same kind of phone list in terms of -- along those lines, Joe?

DR. BOWMAN: Well, this would be --

DR. KHEIFETS: But that would be selective.

DR. BOWMAN: -- email solicited.

DR. OWEN: Email recruitment.

DR. LOTZ: But, I mean, as in the same

way
that we were talking yesterday, about getting the cell phone prefix and calling that?

DR. KHEIFETS: But that wouldn't be selective.

DR. LOTZ: No.

DR. KHEIFETS: I mean, it would be only selective in a way of who answers or who agrees to participate. If you got very poor participation, then you have the same problem of selection, yeah.

DR. OWEN: The reason that we're sharing this, the suggestion on the web-based survey instrument was that, especially, Joe mentioned several times, that, you know, one of the shortcomings was being able to go forward with a cohort and only being able to depend upon billing records.

And one of the -- the proponent -- well, this was Ken Rothman.

DR. KHEIFETS: Um-hmm.

DR. OWEN: And the thing that he -- the case that he was trying to make was that by using that instrument, it would be easy enough, you know, could be designed to be an easy enough, you know, unobtrusive enough instrument that compliance would be high and that you could actually expect your entire cohort to submit themselves to the survey instrument at six-month intervals or --

DR. LOTZ: Well, there was quite a bit of discussion that that instrument would have to take, and not just by him, that if you had an instrument that only

took five to ten minutes, that you might be able to get

people to respond to it every six months, something like that.

DR. KHEIFETS: And then you capture --

DR. LOTZ: Yeah.

DR. KHEIFETS: -- the changes.

DR. LOTZ: That's right. That was the -- that was the rationale.

DR. BOWMAN: There's certainly potential, I think, in the combination of email, phone, internet, to do things like send out an attachment which is basically the interview questionnaire, in its interactive form, and install it on your machine. You answer the questions and you mail it back.

That some investigation of those kinds of approaches, again, a methodologic investigation, to back up your cohort, would make sense to me. Of course, you're already selecting people that have computers and --

DR. KHEIFETS: Um-hmm.

DR. BOWMAN: -- email access. But then again, there's probably fair overlap with that and cell

phone usage.

DR. OWEN: Yeah. There was -- again, it was proposed as a method that would just be, you know, sort of the solution to the problem, you know. But in discussing it, there are a couple things that were clear.

One is that it was -- this was an idea, rather than something that has been developed.

So it would be -- I mean, if you decided to go forward with something like this, you'd be developing that approach, as opposed to using an approach that was already there and known to work. So it would be a lot of methodological --

DR. BOWMAN: Right.

DR. OWEN: -- and piloting kind of work involved probably, if you were to go that direction.

Of course, in a big picture look, you know, it would be the kind of approach that could be used for a lot more than just RF studies.

But another thing that came up that wasn't discussed a lot, the idea did come up, is that it's questionable whether that would truly be feasible. And, you know, even if you got a survey instrument that supposedly only took people ten minutes to fill out as they were connected to the web, you know, what would be the impact of, you know, how slow or how fast your

connection to the web was.

And, you know, maybe -- maybe it seemed like a ten minute survey instrument to you, when you're using your nice company internet connection. But when the member of the cohort's at home on their, you know,

whatever, you know, 1983 circa modem, you know, how much -- how slow is it going to be to do that, and is that going to affect your compliance.

DR. BOWMAN: Yeah.

DR. KHEIFETS: Well, but -- well, then how would he fall off with -- how would he get the cases? How he would ascertain the incidents?

DR. OWEN: I think what he suggested was that the survey instrument would ask general things, like are you taking any medications? Have you been to the hospital for anything in the last six months? Some things like that, which then, if -- they would sort of be like flags that would require direct intervention, follow-up, you know, to --

DR. BOWMAN: But that wasn't Leeka's question.

DR. OWEN: Oh.

DR. BOWMAN: How do you --

DR. KHEIFETS: Well, no. Then, I guess, you know, you go and try to --

DR. OWEN: Oh, how do you assemble the cohort?

DR. KHEIFETS: No, no, no. How do you know --

DR. KACZMAREK: How do you assess the

endpoints?

DR. KHEIFETS: The endpoints.

DR. OWEN: Okay. Yeah. So that's the question I thought I was answering.

DR. KHEIFETS: You know, then I guess if somebody says, I was taking a medication or I went to the hospital, then you go and try to figure out why. And then you're going to lose a lot of people right then in there. And they going to say, forget it, I'm not going to tell you why I went to the hospital, probably. Or maybe. I don't know.

DR. BOWMAN: Yeah. Depending on the people who report the outcomes, sounds like a big problem to me. I mean, you can always get their Social Security number. And if they're in a region with a SEERS registry, use the tumor registry.

DR. KHEIFETS: But then, what was said before, you know, you run into problems if people move around and in and out of the tumor registry. And, you know, whether you're selecting on the cohort, that's going

to be very -- more mobile and you exacerbate that problem too, cause they're --

DR. LOTZ: What happens normal --

DR. BOWMAN: What percent of the country is covered by SEERS?

DR. KHEIFETS: Oh, it's not a big percentage. There are nine regions.

DR. KACZMAREK: The majority of the country, essentially, is not.

DR. KHEIFETS: But they're expanding. I mean, the -- there are other non-SEERS tumor registry in a lot of areas too. I mean, in like in --

DR. BOWMAN: -- California.

DR. KHEIFETS: Yeah, in California and such. But, I mean, they're getting somewhat better. But, certainly, we don't have a complete coverage, and that's a problem.

DR. LOTZ: Ordinarily in a cohort study, how do you track outcomes?

DR. KHEIFETS: Well, it depends. I mean, most of the cohort studies like that, that look at the environmental issues, are retrospective, you know, kind of cohort studies.

DR. LOTZ: Yeah.

DR. KHEIFETS: You know, in -- you know, the big cohort is A-bomb survivors.

DR. LOTZ: Um-hmm.

DR. KHEIFETS: So with them, you just get them back into the -- you know, they do a lot. I mean,

it's an extremely expensive study. They get them back in

and examine them on a regular basis. They're linked to physicians.

There are some cohort studies of populations, like the whole city of Cameron (phonetic)

DR. LOTZ: Right.

DR. KHEIFETS: So they have medical exams to on some --

DR. LOTZ: So in that case, are they maybe even providing the medical exams?

DR. KHEIFETS: They're probably providing, yeah. So -- but it's not -- it's a lot -- it's hard. I mean --

DR. LOTZ: It's intensive and --

DR. KHEIFETS: It's very --

DR. LOTZ: -- expensive to --

DR. KHEIFETS: It's expensive and intensive. I mean, there was a -- I think there was a cohort at Hanford. Was it a case control? I think it was a cohort study where -- so they would -- you know, they were focusing on thyroid cancer. So they would do, you know, they would do exams, palpations, you know, aspirations when they found questionable nodule, and so on

and so forth. So it's very --

DR. BOWMAN: You can use health insurance records, both for active and retired employees. That's

another possibility.

DR. KHEIFETS: That's true. The other possibility is to have a -- I mean, we haven't talked about that. But there --

DR. KACZMAREK: Health insurance can be problematic. People do change their health insurance carriers with some regularity in the U.S. But you could match against general sources, things like the National Death Index, look at overall mortality.

DR. BOWMAN: Right.

DR. KACZMAREK: And that's usually reliably reported.

DR. KHEIFETS: Right.

DR. BOWMAN: And we haven't mentioned that.

DR. KACZMAREK: You would at least know whether your cohort is dead or alive --

DR. KHEIFETS: But what about the population --

DR. KACZMAREK: -- with your overall mortality rates.

DR. KHEIFETS: -- like Kaiser population --

DR. KACZMAREK: Excuse me?

DR. KHEIFETS: What about the population

like taking some large HMOs that do research, like Kaiser population, or something like that.

DR. KACZMAREK: There is a problem of loss to follow-up. The people change their insurance carriers.

DR. KHEIFETS: But it has some advantages, because you get quite a bit of information up front on the individuals. So in terms of cohort enumeration, you get quite a bit of information from, you know -- it's, again, somewhat selective population probably.

Anyway, cohort studies are very hard. Long-term cohort studies are very hard and expensive. So --

DR. OWEN: And the longer they go, the worse the problem of lost --

DR. KACZMAREK: -- to follow up can be --

DR. OWEN: -- follow-up is going to be. Somebody was saying at the other meeting that that was the majority of the cost --

DR. LOTZ: Um-hmm.

DR. OWEN: -- was trying to track it down --

DR. LOTZ: I think Barb was particularly

--

DR. OWEN: -- that people were slipping through the crack.

DR. LOTZ: -- emphasizing that.

DR. OWEN: It was Barb, yeah. Another thing that I got the impression -- this reminds me of somebody here yesterday was pointing out that, you know, if you set up a study like this, where you had, you know, large costs at the beginning to set up your cohort and then things sort of went down and sort of cooked along at this lower rate.

But I got the impression from, maybe it was comments that Barb made at the last meeting, that that's what everybody says, but in practice it doesn't happen that way, that the costs kind of just stay high all the time --

DR. BOWMAN: Right.

DR. OWEN: -- because of unanticipated problems.

DR. LOTZ: There certainly were mixed opinions about that at the previous meeting. And there was definitely people who were saying, yeah, it'll be somewhat -- there is a bolus up front to get start. But

it's not such a low maintenance --

DR. BOWMAN: Right.

DR. LOTZ: -- because you're trying to follow up missing --

DR. BOWMAN: I guess I was mainly

thinking, not so much that, you know, you make the big investment, then you're over the hump, is that you just can't, you know, nibble at it.

You've really got to be aiming at making that initial investment to establish the cohort. And so you have to look at the big picture. You have to make the long-term commitment and be prepared to spend money up front. You just can't salami slice it and jump and get there on small investments.

I'm trying to find other loose ends or pieces that came out of the discussion of that earlier meeting that haven't surfaced here.

DR. BOWMAN: Of course, after you -- you were saying, after you establish the cohort, then the quality of your outcome depends on continuing investment. If you just do a minimum, you're going to have large losses to follow-up. You won't have a lot of exposure data. But if you continue to make investment, then after you get enough person years, you will have a quality outcome.

DR. BEARD: Speaking of other registries, what about the VA? Don't they maintain a tumor registry, and the military services themselves?

DR. LOTZ: The military services

25 themselves, I don't know -- well, I --

DR. BEARD: I'm pretty sure they do for people that are treated within the military.

DR. LOTZ: Oh, yeah, the -- well, I don't know if -- how they're -- I think you're right. There is that.

DR. BEARD: They may later leave the military.

DR. LOTZ: Yeah. And that's where the VA records come into play. And in that case, the records are pretty good. Because if they seek treatment at the VA, then a complete record is there. But, you know --

DR. KACZMAREK: The majority of Veterans actually obtain their care outside the VA system.

DR. LOTZ: That's right. Yeah. It's not -- it's not a high percentage of people.

DR. BOWMAN: Yeah. I don't recall an awful lot of important epidemiologic findings coming out of the military, study of military personnel. So I don't know that whatever records are collected --

DR. BEARD: I just mentioned that because we --

DR. LOTZ: Well, I think one of the reasons for that --

DR. BEARD: -- had talked about the

25 possibility of using the military in some of the case

studies.

DR. LOTZ: I think one of the reasons for that is, you have, essentially, such a young population that isn't in that system any longer, when they get older and there might be more outcomes of interest. So there's --

DR. BOWMAN: You know, the bottom line is that you have to put a lot of work -- you can't just tap into an infrastructure that's been developed for epidemiology.

DR. OWEN: You did remind me of something when you said, tap in. An approach that's used, has been used before, for outcomes, other -- looking at other outcomes, is to try and, you know, shoehorn in questions that are related to the agent of interest.

And we were talking earlier this morning about, you know, is the -- are the neurodegenerative outcomes trackable in any way, you know, in practical terms --

DR. KHEIFETS: Um-hmm. Um-hmm.

DR. OWEN: -- for our consideration. And so I wanted to ask if people were aware of other studies of the etiology of, you know, epi studies, etiology of these neurodegenerative disorders that might be -- you

know, that you're aware are happening or being planned.

DR. KHEIFETS: Yeah, definitely. I mean, there are a lot of studies that are going on. Well, maybe not a lot. But, I mean, there is a study at Stanford on Parkinson's Disease with extensive exposure -- occupational component. I don't know if the RF is part of it or not. And cell phone use, I don't know at all. I don't -- I sort of doubt it.

There is an interesting population in Chicago. They are following nuns and priests. It's a cohort of nuns and priests who have actually have agreed to donate their brains and stuff, eventually. And they have regular follow-ups and they, you know, they actually -- it's a very interesting study. I don't know how much they use --

DR. OWEN: And what's the endpoint for that?

DR. KHEIFETS: Alzheimer's.

DR. OWEN: Alzheimer's.

DR. KHEIFETS: So they are trying -- and probably other neurodegenerative outcomes, but mostly

Alzheimer's. And they going -- they're going to try to, you know, they don't test ongoing -- I think they have yearly exams. They have extremely good participation because these people are really committed and dedicated. And they're going to have brain biopsies, you know, to --

because, you know, there's a large percentage of Alzheimer's that goes undiagnosed. So because Alzheimer's is just diagnosed by exclusion, basically.

So I don't know how much those people use cell phones. I don't know how much they talk to somebody --

DR. BOWMAN: Well, that --

DR. OWEN: Where they're stationed and whether their cloister -- station's not the right term.

DR. BOWMAN: Cloister isn't necessarily right either.

DR. OWEN: I certainly know somebody that was in a situation where he was using a lot of cell phone use because of the type of assignment that he had from the church.

DR. KHEIFETS: So anyway, that's a good -- that's a good study to -- I mean, again, I really -- they're probably not using cell phones a lot. That would be my guess, but I have no idea.

DR. BOWMAN: Yeah.

DR. KHEIFETS: But there are others, I'm sure. But not a lot, but there are others. I mean, in Sweden they --

DR. BOWMAN: With brain cancer?

DR. KHEIFETS: Uh-huh.

DR. BOWMAN: I was wonder if there's anything equivalent to a childhood leukemia study --

DR. KHEIFETS: There are --

DR. BOWMAN: -- and brain cancer.

DR. KHEIFETS: Yeah, there are two -- there is a large study in Japan that includes both leukemia and childhood brain tumors that are -- that's ongoing. And --

DR. OWEN: It has some attempt at RF exposure assessment, doesn't it?

DR. KHEIFETS: Does it?

DR. OWEN: That one.

DR. KHEIFETS: I don't think so.

DR. OWEN: No.

DR. KHEIFETS: I think that it's ELF. They have radon component. But I don't know, given what I've just said, that young people in Japan are not using cell phones that much, according to this. So, I don't know, maybe that's not the population.

DR. LOTZ: You know, that's -- I'm just -- just to mention it, that comment -- you surprised me with that comment yesterday. Because two weeks ago Balzano was talking about how high that he thought the use of cell

phones was in Japan, because of their not spending as much time in cars, so they were in other modes of

transportation where they could. He was --

DR. KHEIFETS: Yeah. I was just there reviewing that particular study. And somebody in the group had mentioned to me that this is -- maybe that it's recent. Maybe they were using the phones so much that now there was prohibition of --

DR. LOTZ: Yeah.

DR. KHEIFETS: But I mean, I noticed it too. On the bus they kept -- I mean, that's for sure, it was forbidden to use it. And they said it was true in the trains and other things.

Somebody specifically told me that they're changing the technology, that there was a big -- but I don't know how true it is.

DR. LOTZ: Well, I don't know either. That was just -- it seemed in contrast to --

DR. KHEIFETS: Yeah.

DR. LOTZ: Because he mentioned Japan specifically.

DR. KHEIFETS: There's a study in Italy of -- but I think it's only leukemia. I don't know that their's has brain cancer, childhood. I'm trying to think if it has brain component; I don't think it does.

But, you know, the -- yeah, I mean, I

would think that you'd have to do a particular study,

because it could get pretty complex.

DR. BOWMAN: But that could be approached by RFP, you know, people doing studies of these disease outcomes with like --

DR. KHEIFETS: Have add-ons.

DR. BOWMAN: Right.

DR. OWEN: Um-hmm.

DR. BOWMAN: Might have cell phone add on.

DR. OWEN: There's precedent for that kind of approach.

DR. KHEIFETS: Sure.

DR. OWEN: It's what we did for invivo approaches through the micronucleus data.

DR. BOWMAN: Um-hmm.

DR. KHEIFETS: Um-hmm.

DR. OWEN: It's actually precedent. I'm about to declare victory here.

Can you, Abiy or Greg, recall any particular notable things from the last meeting that just have been totally absent here, that we might want to throw

out just for reactions?

DR. LOTZ: There hasn't been anything that occurred to me.

DR. OWEN: I mean, if it doesn't pop up in your head, it's probably not --

MR. DESTA: No.

DR. LOTZ: No.

DR. OWEN: I'm not finding much from looking at my notes in that regard. There was a -- okay. Well, we've got -- there was an unusual one that came up, and it is a bit of a side thing. But it got in to IRB approvals and what -- who asked it, Greg? What would you do -- it was a question about data access, data availability and sort of premature data release.

DR. LOTZ: Oh, it was a question, kind of the -- it was more akin to the clinical trial, where you find that your treatment, or the lack, of it, is having a substantial effect, and would you report that? How would you handle reporting that if you, you know, got halfway through the study and saw that the users were having a higher incidence of disease or something like that.

It had partly to do with, what would you plan to do in terms of intermediate analysis along the way, at what intervals, and then what would you do if you found an effect. That was --

DR. KHEIFETS: It's even dangerous in clinical trials to do that. I mean, there have been situations where that has been done, and the answer has never, you know, been definitive, because the child was

stopped in the middle and, you know, then there were

questions whether that was appropriate or not. And it kind of left a lot of people dissatisfied.

DR. LOTZ: Um-hmm.

DR. KHEIFETS: So even with the clinical trial, there's a lot more control of a situation. It's kind of -- I mean, you do your power calculations with the reason that, you know, you're going to need that many cases, that much information before you do something.

And, you know, doing anything halfway, you're always left with --

DR. BOWMAN: Though the power calculation is to what -- how many subjects you need to have confidence in that you're excluding the alternative hypothesis. But if you have a dramatic effect, it can be statistically significant before you, you know, reach that level of power.

DR. KHEIFETS: Usually you get a lot less power than you hoped for at the end of the day, not a lot more only halfway through.

DR. BOWMAN: That's true.

DR. KHEIFETS: And I mean, the thing is that here --

DR. BOWMAN: And certainly --

DR. KHEIFETS: I mean, based on the

information that we have so far, I don't think there's

going to be --

DR. BOWMAN: Right.

DR. KHEIFETS: -- a huge effect that would have to have -- that you'd have to --

DR. BOWMAN: Right.

DR. KHEIFETS: -- stop the study in the middle, I mean, I think.

DR. BOWMAN: And given the whole dynamics of, you know, you set -- you know, you're going to release results at such-and-such a date, there's such a build up, there's so much attention on it. And it really takes a lot of effort to put that together and make sure it's right and to release it. And that has a real cost. It's not something you can just, oh, by the way, we'd like you to do this and, you know, on the existing budget.

DR. OWEN: Okay. Then I'll make a call for outstanding issues, seeing as how I can't come up with any more to --

DR. KHEIFETS: I had a question. Can I ask a question? Was this --

DR. OWEN: Sure. I may not answer it. Oh, it's not my question.

DR. KHEIFETS: Was this commissioned in -- I mean, could you give us little bit sort of background on this? Was this kind of you asked him to review it after

the previous meeting, because --

(UNKNOWN FEMALE SPEAKER): No, no. He's somebody that we're already working with.

DR. KHEIFETS: Okay. So this was not in response to the meeting that was held a couple weeks ago?

(UNKNOWN FEMALE SPEAKER): Not responsive directly to that. But it was intended to be a submission to this --

DR. KHEIFETS: -- process.

(UNKNOWN FEMALE SPEAKER): -- process, yes.

DR. OWEN: So it was prepared absent any real knowledge of what occurred at the last meeting and is based strictly on the literature?

(UNKNOWN FEMALE SPEAKER): Right.

DR. OWEN: Yeah.

DR. KHEIFETS: I was just seeing, the timing was right after that meeting.

DR. OWEN: Yeah.

DR. KHEIFETS: I was wondering whether it was in response to something that occurred at the meeting or not.

DR. BOWMAN: It's a useful letter as a summary.

DR. OWEN: It's a nice succinct summary of

the -- almost as good as some of the ones that Ron referred --

DR. KHEIFETS: You guys are so nice.

DR. BEARD: I have one question related to exposure assessment.

DR. OWEN: Good.

DR. BEARD: I think the comments yesterday, and I know my own situation, we don't appear to have a lot of in depth knowledge of exactly how these cellular systems, at current, work. I mean, as to we're talking about towers. You know, do they modulate their power or are they fixed? The phones, you know, exactly what all the different operating modes are and what the power that may be emanated in those modes are.

Are we particularly concerned about that? Or will the basic metric be the amount of time that you're in the active mode? I mean, how in depth do we need to get into the technical details of the cellular phone system in order to do a good exposure analysis?

DR. OWEN: Well, the feeling that I've gotten is that we've come up with a lot of parameters like that. And that even if we think we know which parameters are more or less important, that there is a lot of merit to actually doing at least some very detailed in depth

study to start with on a formal analysis to determine

which parameters have the most influence.

But backing up from conversations actually at the last meeting with Howard Basset, he pointed out the desirability, perhaps, of incorporating actually the spacial map data, the SAR, you know, at the, you know, within the head, you know, the variation in these exposure assessment studies. Which I was sort of taken aback when he proposed that.

And I think I asked him at the time, well, at least, you know, without maybe having done the work to make this comparison formally, what was his feeling in terms of the relative impact of that variability of that map, compared to the impact of repositioning the phone outside the head.

And I -- as I recall, he -- his gut reaction was that the position of the phone was probably a lot more important or, you know, had a lot more overall influence on the, you know, whatever your bottom line of peak or cumulative exposure would be.

But again, I don't think that that was

based on any kind of an in depth study of that question.

DR. BOWMAN: Are you talking about the details of the electronic mechanisms of the cell phone and the operating system? Or are you talking about other sources of variability or details?

DR. BEARD: No. I'm talking about the details of the electronics and --

DR. BOWMAN: Well, I --

DR. BEARD: But I tend to agree with what Howard said there, is that, you know, the geometry and operator use will have an overriding effect.

DR. BOWMAN: Well, I'm fortunate in the Interphone Study that IARC had recruited a research engineer from French Telecom, who's also doing dosimetry. And he's totally on top of the electronics of their cell phones and their operating system and is very knowledgeable about it in general.

I would certainly, you know, before you get into a study like this in any depth, certainly have someone like that as a consultant, so that you have, you know, all of those details at your command when you need them.

DR. OWEN: Are you referring to Joe --

DR. BOWMAN: Yeah.

DR. OWEN: -- Viart?

DR. BOWMAN: Yeah.

DR. OWEN: So what you're saying is, it might not actually be necessary to do any new studies to answer some of those questions, but that there are --

DR. BOWMAN: Oh, no.

DR. OWEN: -- people who may be able to have the expertise on board?

DR. BOWMAN: I mean, and there's plenty of --

DR. LOTZ: Yeah, I would --

DR. BOWMAN: That's all well known. We've always been able to get answers quite readily to any electronic questions or physical characteristics, electronic characteristics.

DR. OWEN: Have you?

DR. BOWMAN: There's not been any question like that, that I haven't been able to get an -- I mean, I don't always have it in the form I want. But at least I know who to ask to get the data.

DR. LOTZ: Well, I would agree with you that the operators of the systems know how that works, the engineers who designed it. But, yeah, I don't think we've had a very active sort of cross-sharing of that information to, you know, the biological effects --

DR. BOWMAN: Right.

DR. LOTZ: -- research consideration.

DR. BOWMAN: So there's questions like, well, what's the spectrum of the digital signal transmission? That's a question I'd certainly like an

answer to. But there's so much I don't understand about

analyzing digital signals, that I haven't even, you know, been bold enough to ask the question, or, you know, request the data or request the results.

DR. BEARD: I guess -- yeah.

DR. BOWMAN: I don't think that's something that can't be answered. It's just that I'm not sophisticated enough about analyzing digital signals to know and go about doing it.

DR. LOTZ: Well, the other thing related to that, I think in terms of -- certainly in terms of an epidemiologic study, is that we -- I think we do need to try and keep track of what modulation system schemes have been used and what -- with using -- identifying the particular phone should --

DR. BOWMAN: Right.

DR. LOTZ: -- in fact cover that. My sense in the overall aspect of the exposure assessment is that, one, you could go after that kind of information in the piloting exposure assessment studies themselves that we've talked about; but, two, the variability related to those factors is going to be smaller than the other drivers --

DR. BOWMAN: Yeah.

DR. LOTZ: -- in terms of what we're

after.

DR. BOWMAN: So operationally what, like I was saying, is that when you have somebody, an investigator, taking these various exposure assessment surveys, they would just have, as a consultant, if not a co-investigator, an engineer that knows the cell phone systems inside and out, so that that base would be covered with authority.

DR. OWEN: Okay. I'm out.

DR. BOWMAN: It's been a useful meeting.

DR. OWEN: Yeah, it has been a useful meeting. Thank you all for your help with this and for coming out. I look forward to continuing with you on -- in sort of the follow-up phases of this dialogue.

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(WHEREUPON, THE MEETING WAS CONCLUDED FOR THIS DATE AT 11:29 A.M.)

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CERTIFICATE

STATE OF OHIO)
)SS.
COUNTY OF HAMILTON)

I, Debra A. Sprague, a duly qualified and commissioned court reporter and notary public within and for the State of Ohio, do hereby certify that the preceding 141 pages constitute a true, accurate and complete transcription of the meeting held as part of the Cooperative Research and Development Agreement, on the 3rd day of May, 2001.

IN WITNESS WHEREOF, I hereunto set my hand and official seal of office, this 18th day of May, 2001.

_____

DEBRA A. SPRAGUE, CVR
My Commission Expires:
August 12, 2001